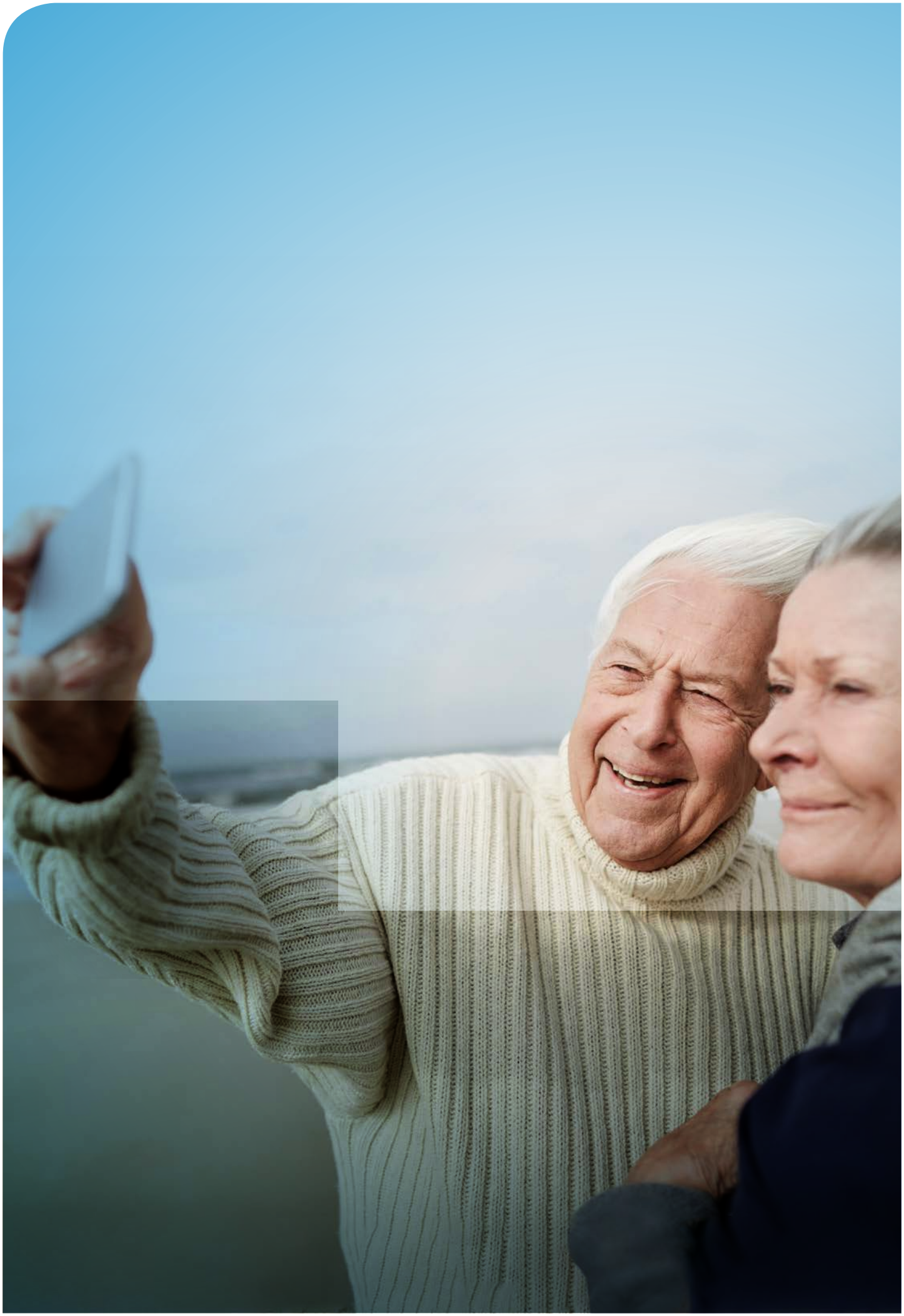
Wellspect®
A REAL DIFFERENCE

INTERMITTENT CATHETERIZATION AND LOFRIC

Using the evidence to guide clinical practice

Wellspect.com



CONTENT

LOFRIC AND SCIENCE

Wellspect HealthCare is behind LoFric – the first hydrophilic catheter developed for intermittent catheterization.

LoFric® has been used by patients requiring intermittent catheterization for over 30 years, and has been thoroughly documented since its introduction on the market. This comprehensive documentation summary includes research studies that show how LoFric works, for both short- and long-term use.

Wellspect HealthCare is a research driven company and scientific evidence is central to the development of our products. All products developed by Wellspect HealthCare undergo a process in which performance and safety are carefully evaluated. We also stay well-informed of the latest research, clinical recommendations and trends in clinical practice. This to ensure we optimize the design and use of our products and realize the benefits for the people who need them.

Why is documentation of urinary catheters so important?

As catheterization is often a lifelong therapy, catheters have to be suitable for long-term therapy. It is important to both protect the urinary tract and avoid infections. This is why a non-infecting and atraumatic technique is a basic principle for catheterization.[1] For someone who relies on catheterization five times a day and/or lack sensation and pain as a warning system, this can mean the difference between serious illness and staying healthy.

- **Clinical documentation is an insurance of a catheter's safety.**
- **Catheters must be suitable for lifelong therapy, it can take years before any complications become evident.**
- **Many users lack sensation, and therefore cannot rely on pain as a warning system.**

CATHETERS AND CATHETERIZATION

Catheterization with a urinary catheter is necessary when there is urine left in the bladder that cannot be emptied through normal voiding, i.e. urinary retention. If not treated, urinary retention may cause infection, incontinence, nocturia and discomfort but also more severe complications such as renal failure and septicaemia. Hence catheterization is a life-saving therapy. Urinary retention can be caused by neurogenic bladder dysfunction; secondary to a lesion to the central and/or peripheral nervous system. Common diagnoses related to neurogenic bladder dysfunction are spinal cord injury, myelomeningocele (spina bifida), multiple sclerosis, Parkinson's disease, diabetes and stroke. Non-neurogenic factors such as from benign prostatic hyperplasia can also cause urinary retention that necessitates catheterization.

The most common complication of all types of catheterizations is urinary tract infection (UTI). The bladder is generally considered a sterile environment but this has recently been challenged.[2] The urinary microbiota seems linked to urinary health[2] and the introduction of a catheter increases the risk of new bacterial contamination and an imbalance. However, it has been known for a long time that keeping the urine inside the body is far more dangerous than using a catheter to get it out.[3]

Intermittent catheterization

Catheterization can either be done using an indwelling catheter or by practicing intermittent catheterization. Intermittent catheterization means 'on demand' emptying of the bladder using a catheter that is removed after each use. An indwelling catheter remains in the bladder with a balloon or other retention mechanism, and is either placed through the abdominal wall (suprapubic indwelling) or through the urethra (transurethral indwelling). While intermittent catheterization is a continence management method that allows normal bladder dynamics similar to normal voiding, an indwelling catheter involves more invasive placement and has a constant in and out flow leaving a static bladder. Complications are more frequently seen with the use of indwelling catheters, and include infections, bladder stones and catheter blockage. This is why intermittent catheterization is the first choice therapy today, both for short- and long-term.[4-9] Suprapubic catheters are only recommended for short-term use and transurethral indwelling catheters should always be avoided and/or their use minimized.[4-6,9,10] Apart from maintaining a good urinary tract health, successful intermittent catheterization means many advantages for the patient. These include improved self-confidence and self-esteem, improved quality of life with less incontinence/urgency, better sleep, making physical activities possible, ability to be sexually active, less pain and discomfort.[e.g.11-14]

LONG-TERM SAFETY OF INTERMITTENT CATHETERIZATION

Single-use hydrophilic catheters were developed in the early eighties to address long-term complications of intermittent catheterization as seen when reusing plastic catheters with add-on lubrication. As reported by Wyndaele and Maes[15] and Perrouin-Verbe et al.[16] the majority of complications related to intermittent catheterization occur after long-term use as a result of damage to the urethral wall from repeated catheterizations. In contrast, long-term use of LoFric hydrophilic catheters is reported to prevent urethral trauma and complications.[17,18]

LoFric documentation: Long-term safety

Håkansson MA, Neovius K, Norrbäck M, Svensson J, Lundqvist T. *Urol Nurs.* 2015;35(5):239-47[19]

Health Care Utilization and Complications Rates among Users Of Hydrophilic-Coated Catheters.

Observational study of catheter-associated complications in 288 long-term (mean of 10 years) LoFric users. The results suggest that LoFric use reduces the risk of complications associated with intermittent catheterization and that users may benefit from a change to LoFric.

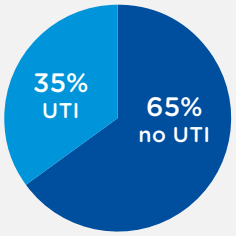
Bakke A, Digranes A, Hoisaeter PA. *Br J Urol.* 1997;79:85-90[17]

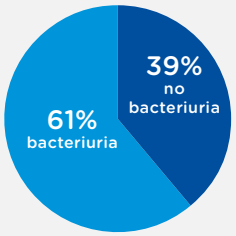
Physical predictors of infection in patients treated with clean intermittent catheterization: 7-year study.

Observational study in 155 LoFric users that provides long-term evidence that intermittent catheterization using LoFric reduces the risk for urethral complications, including UTI. For example, 65% of the patients were UTI-free and 39% had sterile urine after 7 years with LoFric.

Bakke et al. report the results of an observational study of Norwegian patients practicing intermittent catheterization with focus on complications. An initial sample of 302 patients who were previously evaluated 7 years ago were asked for participation. Questionnaires from 170 patients and urine samples from 150 patients were evaluated. Patients in the study had different background; 32% had higher spinal cord injury, 36% had lower spinal cord injury and 31% had bladder dysfunction of unknown etiology. The mean duration of intermittent catheterization was 8 years and 9 months and 91% used LoFric catheters. The results showed that 65% of the patients had no signs of clinical UTI, 35% had signs of clinical UTI (6% with pronounced symptoms and 29% with only minor signs of UTI). Bacteriuria was found in 61% of the urine samples. The dominating species were Escherichia coli for women and gram-positive cocci for men. The publication identifies three main predictive factors for UTIs. 1) Women have more infections, 2) a history of UTI and 3) high catheterization volume increase the risk. Frequency was also found to be predictive for bacteriuria where patients with a low catheterization frequency were less prone to have sterile urine. The study reports that sterile urine was seen in 31% of the patients not using antibiotics and in 54% of those who did.

Figures based on results reported by Bakke et al. 1997[17]





Waller L, Jonsson O, Norlen L, Sullivan L. *J Urol.* 1995;153:345-8[18]

Clean intermittent catheterization in spinal cord injury patients: long-term follow up of a hydrophilic low friction technique.

Retrospective analysis that proposes that long term use of LoFric hydrophilic catheters reduces UTIs and prevents urethral trauma. For example, no new urethral traumas were identified during a 5-9 year follow up of 30 LoFric patients.

"It seems reasonable and is indicated by our study that the hydrophilic catheter regimen has a preventive effect on urethral traumatic complications and that it can facilitate the healing of minor epithelial damage ..."[18]

URINARY TRACT INFECTION (UTI)

Effectiveness of hydrophilic coated catheters has been documented in the scientific literature and there is a general support that they reduce the risk of urological complications such as UTI and trauma (e.g. strictures, hematuria/bleeding).[9,14,20,21] For example, there are five recent meta-analyses available comparing efficacy between hydrophilic-coated and non-hydrophilic catheters[22-26] concluding that use of hydrophilic catheters can reduce the risk of UTI by 16-64%[22-27] and the risk of hematuria by 43%.[25] Summarizing the literature some publications confirm this conclusion,[9,14,20,25,28-34] while others claim that more evidence is needed.[5,14,22,23,35-37] Very few or none conclude the opposite. Comparing UTI incidences reported in the literature gives further support with figures between 40%-60% reported for single-use hydrophilic coated catheters as compared to figures around 70%-80% for non-coated catheters and/or catheter reuse.[38]

Studies investigating UTI incidence are compromised by the facts that different UTI definitions are used, different populations are studied (e.g. patients with spinal cord injury, multiple sclerosis, spina bifida, benign prostate hyperplasia) and different research perspectives are used (e.g. observational surveys, randomized controlled trials). To facilitate comparisons standardized definitions of UTI are proposed.[5,39]

LoFric documentation: Reduced risk of UTI

DeFoor W, Reddy P, Reed M, VanderBrink B, Jackson E, Zhang B, Denlinger J, Noh P, Minevich E, Sheldon C. *J Ped Urol.* 2017:DOI 10.1016/ j.jpurol.2017.06.003[40]
Results of a prospective randomized control trial comparing hydrophilic to uncoated catheters in children with neurogenic bladder.
Randomized controlled trial including 78 children with neurogenic bladder dysfunction comparing hydrophilic-coated to non-coated catheters. Results show lower occurrence of UTI among users of hydrophilic-coated catheters after 1 year, 9% vs 52% (p= 0.003).

Rognoni C, Tarricone R. *BMC Urology*. 2017;17:4[26]
Intermittent catheterisation with hydrophilic and non-hydrophilic urinary catheters: systematic literature review and meta-analyses.
Meta-analysis concluding that the risk of UTI is reduced with the use of hydrophilic-coated catheters as compared to non-coated catheters.

Lamin E, Newman DK. *Int Urol Nephrol*. 2016;48(6):931-9[41]
Clean intermittent catheterization revisited.
Review of intermittent catheterization summarizing important features related to successful intermittent catheterization. It highlights the importance of infection prevention among catheter users and identifies hydrophilic-coated catheters as a cost-effective contributor. It acknowledges that hydrophilic catheters may vary in the quality of coatings and LoFric and the Urotonic™ Surface Technology are described.

"With some instruction, all patients with bladder dysfunction can benefit from [intermittent catheterization] IC ..."[41]

Lucas EJ, Baxter C, Singh C, Mohamed AZ, Li B, Zhang J, Jayanthi VR, Koff SA, VanderBrink B, Justice SS. *J Pediatr Urol.* 2016;12(3):172.e1-8[42]
Comparison of the microbiological milieu of patients randomized to either hydrophilic or conventional PVC catheters for clean intermittent catheterization.
Randomized controlled trial in 50 patients with myelomeningocele. Urine bacteria flora were compared between 25 LoFric users and 25 users of non-coated plastic catheters. After a 1-year follow-up, the results showed a 40% reduction of the average number of potentially pathogenic bacteria in the LoFric group.

Clark JF, Mealing SJ, Scott DA, Vogel LC, Krassioukov A, Spinelli M, Bagi P, Wyndaele JJ. *Spinal Cord.* 2016;54(1):73-7.2015[24]
A cost-effectiveness analysis of long-term intermittent catheterisation with hydrophilic and uncoated catheters.
Health economy evaluation concluding that hydrophilic coated catheters are cost-effective as they are associated with lower number of UTI events, higher life-expectancy and better quality of life as compared to non-coated catheters.

Prieto J, Murphy CL, Moore KN, Fader M.
***Cochrane Database Syst Rev.* Sep 10 2014;9:CD006008**[22,27,43]
Intermittent catheterisation for long-term bladder management.
Meta-analysis of two randomized controlled trials with hydrophilic catheters, whereof one with LoFric. The results propose a 20% risk reduction for UTI with hydrophilic-coated compared to non-hydrophilic catheters. It is however concluded that there is a lack of well-designed trials.

Li L, Ye W, Ruan H, Yang B, Zhang S. *Arch Phys Med Rehabil.* 2013;94:782–7[25]
Impact of hydrophilic catheters on urinary tract infections in people with spinal cord injury: systematic review and meta-analysis of randomized controlled trials.
Meta-analysis of 464 patients from five randomized controlled trials with hydrophilic catheters, whereof three with LoFric. The results propose a 64% risk reduction for UTI with hydrophilic-coated compared to non-hydrophilic catheters.

This meta-analysis combines five randomized controlled trials to create stronger evidence. A meta-analysis follows strict rules on how to search, select, validate, weigh and summarize studies specified in the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-analyses) and by the Cochrane Collaboration. The studies selected for the meta-analysis were all comparing hydrophilic-coated catheters to uncoated plastic catheter in spinal cord injured patients. The following studies were included:

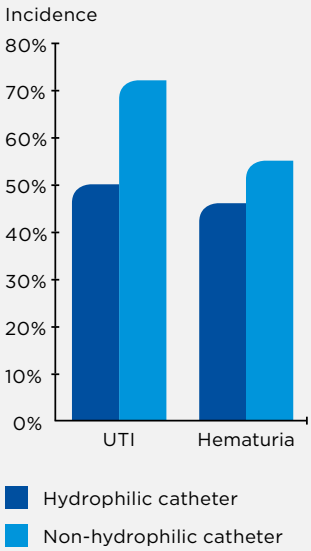
- Cardenas et al. 2011:[29] SpeediCath vs. non-coated plastic catheter in 200 newly injured patients.
- Cardenas and Hoffman 2009:[28] LoFric vs. non-coated plastic catheters in 45 patients with injury more than 6 months ago.
- De Ridder et al. 2005:[30] SpeediCath vs. non-coated plastic catheters in 123 newly injured patients.
- Vapnek et al 2003:[33] LoFric vs. reused non-coated plastic catheters in 63 patients, mainly spinal cord injury.
- Sutherland et al 1996:[44] LoFric vs. non-coated plastic catheters in 33 patients, mainly spinal cord injury.

The publication combines the results from the studies and concludes that UTI incidence was 49.6% in patients using hydrophilic catheters and 72.0% for patients using non-hydrophilic. The results for hematuria (bleeding) were 45.7% (hydrophilic) and 55.0% (non-hydrophilic) but for this comparison only four studies could be used. The results are expressed as ‘odds ratio’ and/or ‘odds’ which is a sort of approximation for risk. The odds ratio for UTI and hematuria decreased for patients on hydrophilic catheters as follows:

- UTI: 0.36; 95% CI 24-54% (p<0.00001).
- Hematuria: 0.57; 95% CI 35-92% (p=0.001).

The figures above could be interpreted as using hydrophilic catheters, compared to non-hydrophilic ones, reduces the expected risk for UTI by 64% and hematuria by 43%.

Graph based on results reported by Li et al. 2013[25]



Cardenas DD, Hoffman JM. *Arch Phys Med Rehabil.* 2009;90(10):1668-71[28]
Hydrophilic catheters versus noncoated catheters for reducing the incidence of urinary tract infections: a randomized controlled trial.
1-year follow-up of 22 LoFric users and 23 users of non-coated plastic catheters, showing evidence of fewer antibiotic treated UTIs in patients using LoFric compared to non-coated catheters.

"... hydrophilic catheter usage was associated with reduced numbers of treated UTIs as compared with standard nonhydrophilic catheters in persons with spinal cord injury ..."[28]

Vapnek JM, Maynard FM, Kim J. *J Urol.* 2003; 169:994-8[33]
A prospective randomized trial of the LoFric hydrophilic coated catheter versus conventional plastic catheter for clean intermittent catheterization.
1-year study on 22 LoFric users and 26 users who reused non-coated plastic catheters. The results showed that the use of hydrophilic catheters are associated with less hematuria and a decrease in the rate of UTI. The study suggests that patients with higher rate of UTI may benefit the most from hydrophilic catheters, and that the lower infection risk is a result of reduced urethral trauma

Bakke A, Digranes A, Hoisaeter PA. *Br J Urol*. 1997;79:85-90[17]
Physical predictors of infection in patients treated with clean intermittent catheterization: 7-year study.
Observational study in 155 LoFric users showing low complication rates associated with LoFric as compared to what is previously reported for non-coated plastic catheters. For example, 65% of the users were UTI-free and 39% had sterile urine after 7 years on LoFric.

Waller L, Jonsson O, Norlen L, Sullivan L. *J Urol*. 1995;153:345-8[18]
Clean intermittent catheterization in spinal cord injury patients: long-term followup of a hydrophilic low friction technique.
Retrospective analysis suggesting that long term use of LoFric hydrophilic catheters reduces UTIs and prevents urethral trauma. For example, no new urethral traumas were identified during a 5-9 year follow-up of 30 LoFric patient.

Bakke A, Vollset SE. *J Urol*. 1993;149(3):527-31[45]
Risk factors for bacteriuria and clinical urinary tract infection in patients treated with clean intermittent catheterization.
Observational 13-month follow-up of 302 users of intermittent catheterization (95% used LoFric) identifying frequent low volume catheterization as a way to reduce the risk of UTI.

Bakke A, Vollset SE, Hoisaeter PA, Irgens LM. *Scand J Urol Nephrol*. 1993;27(1):55-61[46]
Physical complications in patients treated with clean intermittent catheterization.
Observational 13-month follow-up of 302 users of intermittent catheterization (95% used LoFric) concluding fewer and less severe infections associated with LoFric use compared to non-coated plastic catheters with added lubricant. For example, patients using non-coated catheters had a 76% higher infection score.

"A lower infection score was found in the patients (mean score 2.1) using only low-friction catheters (LoFric) compared to those using plain PVC catheters (mean score 3.7) ($p<0.05$)."[46]

Bakke A, Digranes A. *Scand J Infect Dis.* 1991;23(5):577-82[47]
Bacteriuria in patients treated with clean intermittent catheterization.
Observational 13-month follow-up of 302 users of intermittent catheterization (95% used LoFric) concluding low frequency of UTI with hydrophilic catheters (LoFric). For example, 86% of patients showed no clinical signs of UTI during the study period. The study suggests that the use of antibiotics in patients using intermittent catheterization should be minimized and supports a frequency of more than 4 catheterizations per day to keep bladder volumes low and reduce the risk of UTI.

TRAUMA

Intermittent catheterization has very few contraindications, but the scientific literature recommends lubrication of the catheter to avoid trauma.[14,48,49] This recommendation is due to the complications seen after long-term use. These complications are related to damage to the urethral wall from repeated catheterizations[15,16] and the fact that urethral trauma as such is associated with an increase in UTI risk.[11,46,50,51] Damage to the urethra is more likely to occur with an un-lubricated catheter,[52] and findings reported in the literature support the use of hydrophilic catheter to reduce the risk of hematuria/urethral trauma.[e.g.14,20,25,32] LoFric in particular seems to be able to reduce the risk of hematuria by 48%.[53] The reported incidence of trauma varies depending on the evaluation method (e.g. self-reported bleeding, microscopic observations) and the study set-up, but the literature suggests general figures between 20-30% for patients practicing intermittent catheterization.[e.g.29,33,38,54]

LoFric documentation: Reduced risk of trauma

Rognoni C, Tarricone R. *BMC Urology*. 2017;17:4[26]
Intermittent catheterisation with hydrophilic and non-hydrophilic urinary catheters: systematic literature review and meta-analyses.
Meta-analysis suggesting that the risk of hematuria may be different between brands of hydrophilic-coated catheters and that LoFric seems to lower the risk.

Rognoni C, Tarricone R. Bocconi University. *CERGAS Center for Research on Healthcare and Social Management.* 2016[53]
Clinical and economic evaluation of LoFric® catheters for the management of bladder dysfunctions.
Meta-analysis concluding that the risk of hematuria is 48% lower with the use of LoFric as compared to non-coated catheters.

Li L, Ye W, Ruan H, Yang B, Zhang S. *Arch Phys Med Rehabil*. 2013;94:782–7[25]
Impact of hydrophilic catheters on urinary tract infections in people with spinal cord injury: systematic review and meta-analysis of randomized controlled trials.
Meta-analysis of 464 patients from five randomized controlled trials with hydrophilic catheters, whereof three with LoFric. The results conclude a 43% risk reduction for hematuria with hydrophilic-coated compared to non-hydrophilic catheters.

Stensballe J, Looms D, Nielsen PN, Tvede M. *Eur Urol*. 2005;48(6):978-83[55]
Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: a prospective, randomised, participant-blinded, crossover study of three different types of catheters.
Cross-over study of LoFric and other hydrophilic/non-hydrophilic catheters in 40 healthy volunteers showing evidence of less microscopic hematuria and pain with LoFric. For example, frequency of hematuria was 40% for LoFric, 58% for SpeediCath and 67% for Incare Advance.

Vapnek JM, Maynard FM, Kim J. *J Urol.* 2003; 169:994-8[33]
A prospective randomized trial of the LoFric hydrophilic coated catheter versus conventional plastic catheter for clean intermittent catheterization.
1-year study of 22 LoFric users and 26 users who reused non-coated plastic catheters. The results showed that the use of hydrophilic catheters are associated with less hematuria and decrease in the rate of UTI. For example, no hematuria was reported for the LoFric group while mild hematuria was reported for the control group.

This randomized controlled trial compared the use of LoFric to a non-coated plastic catheter for intermittent catheterization. The study included 62 patients, mainly with spinal cord injury, and the follow up period was 12 months. One patient was removed from analysis due to wrongful treatment and thirteen patients were lost during the follow up. Thus, 22 patients used LoFric for 12 months and 26 used non-coated plastic catheters for 12 months. In the hydrophilic-group, patients were given 120 catheters/month (4 per day) while in the PVC-group 30 catheters were given per month (1 per day) with the instructions to clean and reuse. The results showed twice as high hematuria score among the non-coated catheter users as compared to the hydrophilic-group where no significant hematuria was seen. Decrease in UTI rate in the hydrophilic-group was seen between baseline and follow up (0.44 to 0.14 monthly per patient). In the non-coated catheter group the UTI incidence remained more or less at the same level throughout the study (0.20 to 0.14 monthly per patient). The study reports of high patient satisfaction with LoFric catheters. The publication concludes that the use of hydrophilic catheters is associated with less hematuria and a decrease in the rate of UTI as compared to non-coated catheters. It proposes that patients with higher rate of UTI may benefit the most of hydrophilic catheters, and that the lower infection risk is a result of reduced urethral trauma.

Hedlund H, Hjelmas K, Jonsson O, Klarskov P, Talja M. *Scand J Urol Nephrol.* 2001;35(1):49-53[21]
Hydrophilic versus non-coated catheters for intermittent catheterization.
Review of hydrophilic coated catheters including primarily LoFric studies, concluding evidence on decreased urethral irritation.

Sutherland RS, Kogan BA, Baskin LS, Mevorach RA. *J Urol.* 1996;156:2041-3[44]
Clean intermittent catheterization in boys using the LoFric catheter.
2-month study of 16 LoFric-users and 14 users of non-coated plastic catheters showing evidence of less hematuria with LoFric. For example, 9 episodes of hematuria were detected in 6 subjects who used LoFric and 19 episodes were detected in 11 subjects in the control-group after 2 months of use. Furthermore, the study reports that the LoFric-group scored higher convenience and insertion comfort than the control-group and that 81% wished to continue with LoFric.

Vaidyanathan S, Soni BM, Dundas S, Krishnan KR. *Paraplegia.* 1994;32(7):493-500[56]
Urethral cytology in spinal cord injury patients performing intermittent catheterisation.
Study on 17 LoFric users, 14 users of a non-coated plastic catheter, and 11 users of an indwelling catheter. The results show evidence of LoFric causing less urethral inflammation and fewer numbers of bacteria than for those who use a non-coated plastic catheter or a urethral indwelling catheter. For example, a more than 10-fold increase in urethral inflammatory response was seen with non-coated catheters compared to LoFric.

Hellstrom P, Tammela T, Lukkarinen O, Kontturi M. *Eur Urol.* 1991;20(2):117-21[57]
Efficacy and safety of clean intermittent catheterization in adults.
40-month follow up study of 41 LoFric users presenting evidence on the low incidence of urethral complications associated with LoFric. For example, no cases of urethral trauma were observed during the study period and few patients had repeated UTIs (9.8%).

"The LoFric catheter was associated with less microscopic hematuria ..."[44]

"... 13 of the 16 LoFric users (81%) desired to continue its use ..."[44]

"... use of a LoFric catheter for intermittent catheterization was associated with significantly lesser degree of urethral inflammatory response ..."[56]

FRICTION

A recent review acknowledges that there are variations in the quality of coatings among hydrophilic catheters and proposes osmolality as one important factor to consider when comparing different hydrophilic catheters.[41] It has been concluded that the outer layer of the hydrophilic coated catheter should possess the same osmolality as the urine[58] and that high osmolality hydrophilic catheters are recommended to minimize risk of urethral trauma, catheter sticking and patient discomfort.[59]

The LoFric catheter is characterized by the Urotonic™ Surface Technology. This means that the catheter has a surface layer isotonic to urine, i.e. the salt concentration of the catheter's surface is in balance with the urine. Isotonic osmolality prevents removal of the hydrophilic coating from the surface. This is essential for keeping high lubricity and minimal friction between catheter and urethra during the entire catheterization process, including withdrawal. According to peer-reviewed data, LoFric with the Urotonic Surface Technology is the only available hydrophilic coated catheter that could demonstrate high osmolality (i.e. ~900 mOsm/kg[58]) that corresponds to osmolality levels normally present in urine (i.e. 800-1200 mOsm/kg[60,61]). This may be one contributing factor to the low complication rates associated with long-term LoFric use found in real-life evidence.[19] A recent meta-analysis has identified a unique hematuria risk reduction of 48%, only applicable for the LoFric-brand.[26,53]

LoFric documentation: Low friction

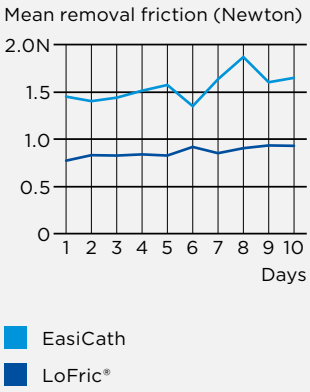
Jones DS, Garvin CP, Gorman SP. J *Mater Sci Mater Med*. 2001;12(1):15-21[62]
Design of a simulated urethra model for the quantitative assessment of urinary catheter lubricity.
In vitro study of LoFric and other hydrophilic catheters presenting evidence on low insertion/withdrawal friction.

Lundgren J, Bengtsson O, Israelsson A, Jonsson AC, Lindh AS, Utas J. *Spinal Cord.* 2000;38(1):45-50[59]
The importance of osmolality for intermittent catheterization of the urethra.
Histology study in rabbit showing evidence of lower friction and less epithelial cell damage with the high osmolality LoFric catheter.

Waller L, Telander M, Sullican L. *Spinal Cord*. 1997;35(4):229-33[58]
The importance of osmolality in hydrophilic urethral catheters: a crossover study.
Cross-over study of LoFric and another hydrophilic catheter in 14 users providing evidence that high osmolality of the hydrophilic coating results in less sticking and lower withdrawal friction. For example, 3 incidents of sticking were observed in 2 patients among LoFric users while 42 incidents of sticking were observed in 9 patients among users of another hydrophilic catheter.

This cross-over study investigates 14 male spinal cord injured patients who tested LoFric and another hydrophilic catheter (EasiCath) for ten days in a randomized order. Removal friction was measured, and although both had hydrophilic coating, LoFric with its high osmolality showed 55% lower removal friction ($p<0.001$). Events of catheter-sticking inside the urethra were different with 3 incidents in 2 patients among LoFric-users compared to 42 incidents in 9 patients among users of the other hydrophilic catheter. An inverse correlation between osmolality measurements was reported. Osmolality measurement reported 900 and 950 mOsm/kg for LoFric and 15 and 80 mOSm/kg for the other hydrophilic catheter.

Graph based on results published in Waller et al. 1997[58]



PATIENT PREFERENCE

Patient compliance or adherence is a key factor for ensuring good clinical outcome.[63] For this reason, non-compliance is related to a significant financial burden to the healthcare system and society with an estimated cost of about $100 billion each year in the US, affecting 30-50% of all patients, irrespective of diagnosis or setting.[63] Several factors affect adherence, and shared decision-making between doctor and patient has been recommended as a way to improve initial embracement of a treatment or a therapy.[63] Long-term adherence is dependent on whether the therapy fits into everyday life for the patient, and emphasis should be on finding treatment options that work well with life style and are easy to use.[64]

For intermittent catheterization therapy, adherence is partly reached by a free and adapted choice of catheter as described in several publications.[14,23,32,49,65-68] The greatest barriers for practicing intermittent catheterization are reported to be inconvenience related to preparations[69] and access to bathrooms.[54,65,70] Under such circumstances use of a convenient and neat catheter may improve adherence.[52] It is however essential to fully understand patients' catheter preferences to optimize compliance. Previous research has concluded that UTI risk reduction, ease of insertion, and convenience are the most appreciated attributes for intermittent catheters among patients.[71,72] There is also a general clinical recommendation to consider personal preference, comfort, and ease of use in a patient's catheter choice.[41,43] Ease of use, comfort, and preference related to hydrophilic catheters have been documented by several authors.[20,23,30,33,70] When a catheter choice is available, about 70-81% of patients prefer hydrophilic catheters[20,73,74] and 71% of patients prefer not to reuse non-coated plastic catheters.[75]

Patient preference is the cornerstone of the LoFric-assortment of hydrophilic catheters with extensive research as a driver in the product development.

LoFric documentation: Patient preference

Koeter I, Stensröd G, Hunsbedt Nilsen A, Lund R, Haslam C, De Sèze M, Sriram R, Heesakkers J, the LoFric Origo study group. Nursing Open. 2018 doi.org/10.1002/nop2.193[76]

User perception of a new hydrophilic-coated male urinary catheter for intermittent use

Observational survey including patients' preferences and opinions from 365 users evaluating LoFric Origo for 8 weeks. The results show that LoFric Origo fulfils patient preferred catheter requirements associated to infection prevention, ease of insertion, and convenience. For example,
- 85% perceived the catheter as hygienic due to the insertion grip and 81% found the insertion grip easy to use.
- 83% found it to be easy to use during insertion
- 67% deemed the foldable feature as important
- 89% found the slim catheter design appealing
In total, this resulted in good adherence and 85% would recommend LoFric Origo to a friend.

Wilson M. *Br J Nurs.* 2015;24(2):76-85[77]

Clean intermittent self-catheterisation: working with patients.

Expert statement describing important aspects of teaching intermittent catheterization. LoFric Origo and LoFric Sense are mentioned as catheters that may help patients practicing the technique correctly.

"... 81% found the disposable catheter [LoFric] to be more convenient and 88% thought it was easier to handle."[73]

Woodward S. *Br J Neurosci Nurs.* 2013;9(3):114-9[78]

Improving quality of life for men using intermittent self-catheterisation.

Expert statement describing the advantages of intermittent catheterization with LoFric and other hydrophilic catheter. For example, LoFric (and other hydrophilic catheters) can promote independence and improve quality of life.

"... if given a choice most patients will prefer to use the pre-lubricated catheter [LoFric] ..."[73]

Sallami S, Mouine Y, Rhouma SB, Cherif K, Dahmani A, Horchani A. *Urotoday Int J.* 2011;4(1):art7[79]

Clean intermittent catheterization following urethral stricture surgery using a low friction catheter versus conventional plastic catheter: A prospective, randomized trial.

A 2-year follow-up of 31 LoFric users and 28 users of non-coated catheters. The results showed more satisfaction, increased comfort, and higher quality of life among LoFric users.

Taskinen S, Fagerholm R, Ruutu M. *J Pediatr Urol.* 2008;4(5):367-71[80]

Patient experience with hydrophilic catheters used in clean intermittent catheterization.

Evaluation of 100 hydrophilic catheter users showing good insertion and removal properties (85-90%) for LoFric.

Bjerklund Johansen T, Hulting C, Maderbacher H, Del Popolo G, Amarenco G, LoFric Primo Study Group. *Eur Urol.* 2007;52(1):213-20[81]
A novel product for intermittent catheterisation: its impact on compliance with daily life-international multicentre study.
A 2-week study of 378 LoFric-users reporting high satisfaction rates. For example, LoFric was shown to improve patients' ability to comply with everyday life and 74% of patients previously using non-coated catheters wished to continue with LoFric.

Litherland AT, Schiotz HZ. *Br J Nurs.* 2007;16(5):284-7[82]
Patient-perceived discomfort with two coated urinary catheters.
Prospective study of 196 hydrophilic catheter users reporting low levels of discomfort with LoFric.

Fader M, Moore KN, Cottenden AM, Pettersson L, Brooks R, Malone-Lee J. *BJU Int.* 2001;88(4):373-7[83]
Coated catheters for intermittent catheterization: smooth or sticky?
Evaluation of 61 hydrophilic catheter users presenting examples of minimized discomfort with LoFric.

Lopez Pereira P, Martinez Urrutia MJ, Lobato L, Rivas S, Jaureguizar Monereo E. *Actas Urol Esp.* 2001;25(10):725-30[74]
Comparative study of the degree of patient satisfaction in intermittent catheterization with Lofric and polyvinyl chloride catheters.
2-month study of 35 LoFric users demonstrating evidence of higher satisfaction among LoFric-users compared to patients using non-coated catheters. For example, 83% of those who experienced withdrawal discomfort reported that this disappeared with LoFric and 86% found LoFric easy or very easy to learn and use.

This prospective study involved 40 spina bifida patients who tried out LoFric for a 2-month period and reported satisfaction using a questionnaire. Patients represented both sexes and had previous experience of performing intermittent catheterization with a non-coated catheter. A total of 86% found LoFric easy to learn. Of the 51% who reported problems with their previous catheter, 72% found these to be resolved by LoFric use. The LoFric catheter was favored by 70% for its ability to reduce discomfort compared to the non-coated catheter. The study concluded that LoFric provided an increase in both comfort and patient satisfaction.

83% with previous withdrawal discomfort had it disappear with LoFric.[74]

86% found LoFric easy or very easy to learn and use.[74]

Pascoe G, Clovis S. *Br J Nurs.* 2001;10(5):325-9[84]
Evaluation of two coated catheters in intermittent self-catheterization.
Cross-over study with 25 users testing LoFric and SpeediCath catheters for 1 week each. The results showed examples of good insertion and removal properties with LoFric. Approximately 90% of LoFric users found the catheter comfortable to insert and easy to remove.

Mauroy B, Soret R, Bonnal JL, Fantoni JC. *Ann Urol. (Paris)* 2001;35(4):223-8[85]
(Comparison of 3 self lubrificated urethral catheters: prospective study on 27 patients).
Prospective, randomized study in 27 users who evaluated LoFric and 2 other hydrophilic catheters. The results showed high satisfaction for LoFric with regard to catheter management, insertion/withdrawal properties and performance.

Montagnino B. *Urol Nurs.* 2000;20(4):247-9, 253[86]
The LoFric catheter: new technology improves an old technique.
Review of the overall benefits of using LoFric instead of non-coated catheters for intermittent catheterization.

Pachler J, Frimodt-Møller C. *BJU Int.* 1999;83:767-9[87]
A comparison of prelubricated hydrophilic and non-hydrophilic polyvinyl chloride catheters for urethral catheterization.
Cross-over study with 32 users who tested LoFric and a non-coated catheter for 3 weeks each. The results showed a trend toward easier management and preferences for the LoFric catheter.

Sutherland RS, Kogan BA, Baskin LS, Mevorach RA. *J Urol.* 1996;156(6):2041-3[44]
Clean intermittent catheterization in boys using the LoFric catheter.
2-month study of 16 LoFric users and 14 users of non-coated catheters showing evidence of less hematuria with LoFric. The study reports that the LoFric group scored higher convenience and insertion comfort than the control group and that 82% wished to continue with LoFric.

Diokno AC, Mitchell BA, Nash AJ, Kimbrough JA. *J Urol.* 1995;153(2):349-51[73]
Patient satisfaction and the LoFric catheter for clean intermittent catheterization.
1-month study of 41 LoFric-users showing evidence of high satisfaction. For example, 81% preferred LoFric and found it more convenient and favorable than their previous non-coated catheter and 88% found it easier to handle.

DILATATION AND STRICTURE TREATMENT

A urethral stricture is an abnormal narrowing of the urethra and is often caused by trauma or inflammation.[88] As catheterization is one cause of strictures, non-traumatic catheterization technique and catheter material are essential parts in preventing the occurrence of these complications.[89] Common treatment methods for urethral strictures are urethrotomy and intermittent catheterization/dilatation.[79,88,90]

Urethrotomy is an endoscopic surgical procedure that dilates the urethra, and it is performed in a medical center under local anesthesia. Intermittent catheterization/dilatation can be learned and performed at home. Recurrence rates for strictures are between 40-80%[79] but intermittent catheterization/dilatation has been reported to reduce recurrence.[79,90] For example, Elhaj et al. report of lower stricture recurrence rates among patients who practiced intermittent catheterization (77.41% versus 19.35%).[90] There is a significant impact on patients' quality of life when experiencing and treating strictures[91] which is why it is important to use treatment alternatives that optimize comfort and reduce pain.

LoFric documentation: Stricture treatment

Rijal A, Little B, McPhee S, Meddings RN. *Nepal Med Coll J.* 2013;15(1):46-9[92]
Bladder outflow problems in females.
Study of 188 females with bladder outflow problems showing an example on LoFric use to successfully treat and prevent recurrent urethral strictures.

Sallami S, Mouine Y, Rhouma SB, Cherif K, Dahmani A, Horchani A. *Urotoday Int J.* 2011;4(1):art 7[79]
Clean intermittent catheterization following urethral stricture surgery using a low friction catheter versus conventional plastic catheter: A prospective, randomized trial.
A 2-year follow-up of 31 LoFric-users and 28 users of non-coated plastic catheters investigating prevention and/or treatment of recurrent strictures after endoscopic urethrotomy.

This randomized controlled study compared the use of LoFric or non-coated catheters for intermittent catheterization treatment of strictures after endoscopic urethrotomy. The study included 62 men, 41 treated for their first stricture and 21 with recurrent problems. All patients had an indwelling catheter placed after surgery and were taught intermittent catheterization 2 weeks later. The patients were followed for 2 years and each patient evaluated their catheter use with a questionnaire. Three patients from the control group failed to follow-up. There were no differences detected between the catheters with regard to convenience or in how troublesome the catheterization was. However, patients found the LoFric catheter to generate less pain (22.6% vs. 64.5% of patients), higher comfort, and better general satisfaction (71% versus 32.2%). The study concluded that the LoFric catheter decreased pain, and increased comfort and satisfaction compared to a non-coated catheter. For this reason, LoFric should be considered as a better option for prevention of urethral strictures from a quality of life aspect.

Table based on results reported in Sallami et al. 2010[79]

Mean questionnaire score* (standard deviation) and number of reported complications

	LoFric (n = 31)	Non-coated catheter (n=28)
Troublesome catheterization	3.46 (1.68)	5.38 (1.36)
Convenience	4.96 (1.20)	5.82 (1.50)
Pain	2.15 (1.18)	7.78 (1.92)**
Comfort	2.07 (1.12)	5.89 (1.95)**
General satisfaction	1.85 (0.55)	7.05 (1.41)**
Complications		
- Prostatitis	0	1
- Bleeding	0	2
- Bacteriuria	1	4
- Stricture recurrence	2	7

*0 = most favorable
5 = indifferent
10 = unfavorable**p-value <0.05

Lauritzen M, Greis G, Sandberg A, Wedren H, Ojdeby G, Henningsohn L. *Scand J Urol Nephrol.* 2009;43(3):220-5[93]

Intermittent self-dilatation after internal urethrotomy for primary urethral strictures: a case-control study.

Observational study of 55 users of hydrophilic catheters and 162 control patients followed during a 3-6 year period. Results showed evidence of the preventive effects of intermittent self-dilatation (ISD) on stricture recurrence. For example, stricture recurrence was 8% among those who practised ISD with hydrophilic catheters and 32% in the control group. The median time to first recurrence was 2 years for the ISD group and 6 months for the control group.

"Postoperative intermittent self-dilatation effectively reduces the relative risk of recurrence of a new urethral stricture after internal urethrotomy from 32%...to 8%."[93]

Harriss DR, Beckingham IJ, Lemberger RJ, Lawrence WT. *Br J Urol.* 1994;74(6):790-2[94]

Long-term results of intermittent low-friction self-catheterization in patients with recurrent urethral strictures.

6-36 month study of 101 LoFric users showing evidence that LoFric is a safe and effective way to prevent stricture recurrence long-term (>12 months).

"... intermittent low-friction self-catheterization is safe and effective in preventing stricture recurrence in the long term."[94]

Kjaergaard B, Walter S, Bartolin J, Andersen JT, Nohr S, Beck H, Jensen BN, Lokdam A, Glavind K. *Br J Urol.* 1994;73(6)692-5[95]

Prevention of urethral stricture recurrence using clean intermittent self-catheterization.

1-4 year study of 31 LoFric users and 24 control patients that provides evidence for the use of LoFric to effectively reduce the frequency of recurrent urethral strictures. For example, 68% of patients not treated with intermittent catheterization experience recurrent strictures during the first year after urethrotomy compared to 19% in the LoFric-group.

"Weekly clean intermittent catheterization is a simple method of reducing the frequency of urethral stricture recurrence after internal urethrotomy."[95]

Bodker A, Ostri P, Rye-Andersen J,Edvardsen L, Struckmann J. *J Urol.* 1992;148(2 Pt 1):308-10[96]

Treatment of recurrent urethral stricture by internal urethrotomy and intermittent self-catheterization: a controlled study of a new therapy.

12-month follow-up of 23 patients practicing intermittent catheterization with LoFric (refers to abstract by Lawrence et al, 1991 and Zambon et al, 1990 on the use of LoFric) and 28 control patients. The study shows no recurrent strictures in patients who are actively practicing intermittent catheterization in order to prevent urethral strictures.

" ... for the treatment of recurrent urethral stricture clean intermittent self-catheterization following internal urethrotomy should be continued for a long duration, possibly permanently."[96]

Robertson GS, Everitt N, Lamprecht JR, Brett M, Flynn JT. *Br J Urol.* 1991;68(1):89-92[97]

Treatment of recurrent urethral strictures using clean intermittent self-catheterisation

6-month study of 65 patients with LoFric showing evidence of treating and preventing recurrent urethral strictures.

Lawrence WT, MacDonagh RP. *J R Soc Med.* 1988;81(3):136-9[98]

Treatment of urethral stricture disease by internal urethrotomy followed by intermittent 'low-friction' self-catheterization: preliminary communication.

Preliminary results of Harriss et al. 199492 showing that postoperative urine flow-rates can be maintained if "low-friction" catheterization with LoFric is adopted.

INSTILLATION

Bladder instillation is used for local administration of drugs into the bladder. This is used for treatment of interstitial cystitis and cancer, for example. Drugs are delivered via catheters, and a hydrophilic-coated surface such as that of the LoFric catheters reduces the risk for trauma associated with instillation therapy.

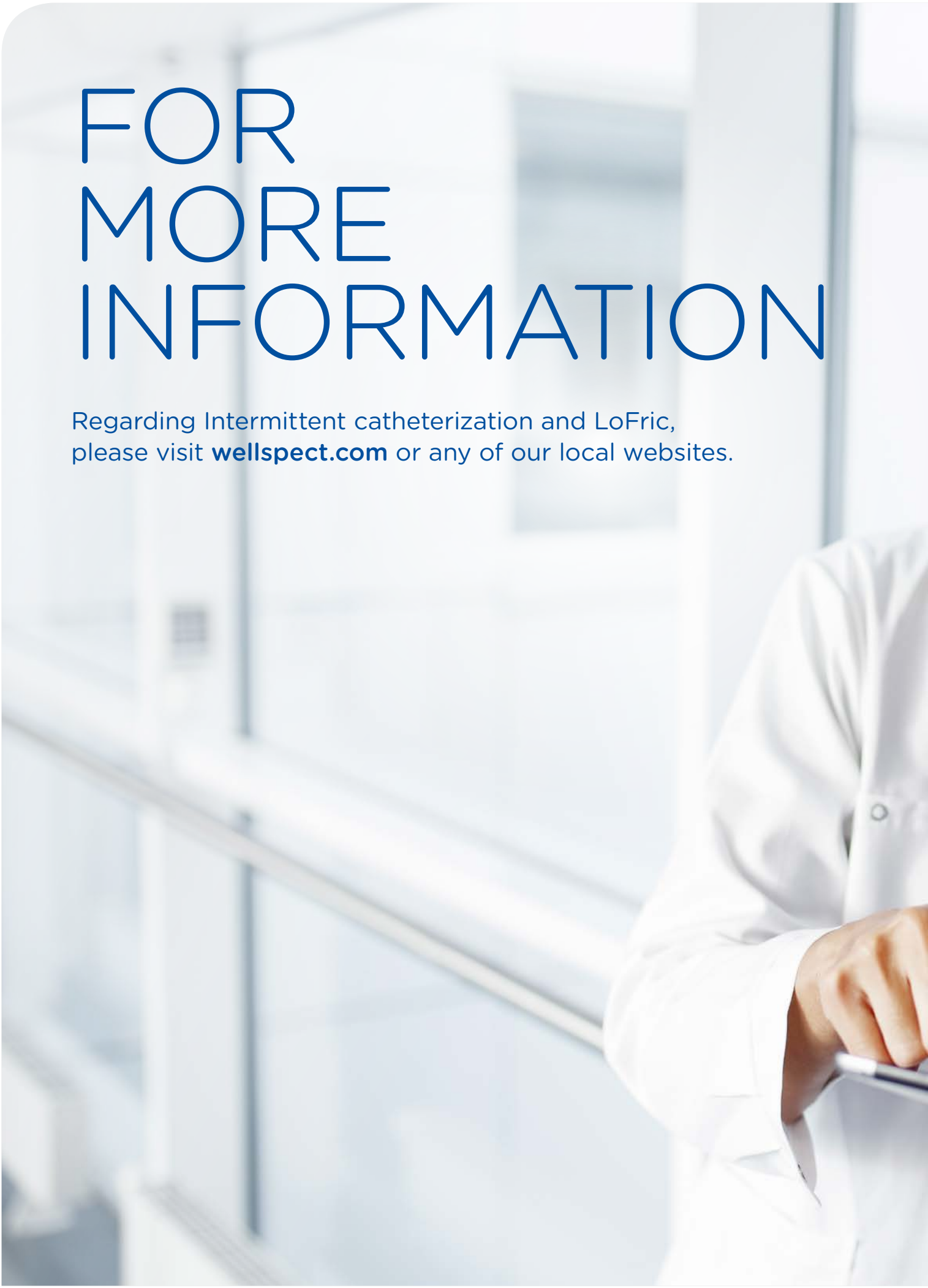
LoFric documentation: Instillation therapy

Dell JR, Parsons CL. *Reprod Med.* 2004;49(3 suppl):243-52[99]
Multimodal therapy for interstitial cystitis.
Review of treatment of interstitial cystitis including examples of the use of LoFric catheters for intravesical instillation.

Saad A, Oakes G, Thompson AC, Hanbury DC, McNicholas TA, Boustead GB, Woodman AC. *UroOncology.* 2002;2(1):23-26[100]
Delaying the Administration of Intravesical Chemotherapy Improves its Dwell Time.
Study of 42 patients who had chemotherapy instilled in the bladder with LoFric.

FOR MORE INFORMATION

Regarding Intermittent catheterization and LoFric, please visit **wellspect.com** or any of our local websites.



COST-EFFECTIVENESS

Today there is an increasing focus on costs due to restrictions in healthcare budgets and more people needing access to the healthcare systems. Costs are often highlighted, also when it comes to catheter choice in intermittent catheterization[23,24] and there are increasing demands for data showing cost-effectiveness.[22] Today there are several published per-reviewed cost-effectiveness analyses investigating value of hydrophilic coated catheters, using several different healthcare settings.[23,24,101-106] The most recent ones conclude that hydrophilic coated catheters are cost-effective as they can reduce the number of UTI and other catheter-related complications and increase quality of life for the user.[24,101-106] In addition, a recent review of intermittent catheterization acknowledges the fact that there may be increasing costs related to new improved catheters but that the therapy remains cost-effective.[41]

Cost-effectiveness of hydrophilic coated catheter is strongly linked to available clinical evidence and long-term data. LoFric data, as described in previous sections, significantly contributes to the conclusion of cost-effectiveness of hydrophilic-coated catheters made in the publications above. This in combination with the unique LoFric long-term safety data described in previous sections, suggest that LoFric is a cost-effective choice for the healthcare system and for users of intermittent catheterization.

LoFric documentation: Cost-effectiveness

Welk B, Isaranuwatchai W, Krassioukov A, Husted Torp L, Elterman D. *J Med Econ.* 2018;15:1-10. doi: 10.1080/13696998.2018.1443112.[105]
Cost-effectiveness of hydrophilic-coated intermittent catheters compared with uncoated catheters in Canada: a public payer perspective.
Health economy evaluation suggesting cost-effectiveness and reimbursement of hydrophilic-coated catheters for intermittent use. Hydrophilic-coated catheters seem to reduce UTIs and increase quality of life at a reasonable additional cost when compared to uncoated catheters.

Truzzi JC, Teich V, Pepe C. *Int Braz J Urol.* 2018;44:121-131.[103]
Can hydrophilic coated catheters be beneficial for the public healthcare system in Brazil? - A cost-effectiveness analysis in patients with spinal cord injuries.
Health economy evaluation concluding that the use of hydrophilic-coated catheters is a cost-effective treatment from the perspective of the Brazilian public healthcare system.

Watanabe T, Yamamoto S, Gotoh M, Saitoh T, Yokoyama O, Murata T, Takeda M. *Low Urin Tract Symptoms.* 2017;9(3):142-150.[104]
Cost-Effectiveness Analysis of Long-Term Intermittent Self-Catheterization with Hydrophilic-Coated and Uncoated Catheters in Patients with Spinal Cord Injury in Japan.
Health economy evaluation concluding that hydrophilic-coated catheters for intermittent use can be considered highly cost-effective in Japan compared with uncoated catheters. This, as hydrophilic-coated catheters reduce UTIs and increase quality of life at a reasonable additional cost.

Rognoni C, Tarricone R. *BMJ Open.* 2017 Jan 17;7(1):e012360.[102]
Healthcare Resource Consumption for Intermittent Urinary Catheterisation: Cost-Effectiveness of Hydrophilic Catheters and Budget Impact Analyses.
Health economy evaluation concluding that hydrophilic-coated catheters for intermittent catheterization are cost-effective when considered over a lifetime. The hydrophilic-coated catheters seem to provide health benefits by reducing treatment-related complications at a reasonable additional cost.

Håkansson MA, Neovius K, Lundqvist T. *Urol Nurs.* 2016:36(5):233-42[106]
Healthcare costs associated to hydrophilic coated and non-coated urinary catheters for intermittent use in the United States.
Health economic evaluation comparing hydrophilic-coated to non-coated catheters for intermittent catheterization. The results showed that life-long use of hydrophilic-coated instead of non-coated catheters avoids on average 18 complications and reduces healthcare cost by $10,184 per patient.

This health economic evaluation uses a Markov model to estimate lifetime costs and catheter-related complications in a U.S. setting. By modelling a lifetime use of intermittent catheterization and starting at the age 40, substantial healthcare costs and complications were identified. However, the use of hydrophilic-coated instead of non-coated catheters avoided on average 18 complications per patient. This translated into a total cost saving for the healthcare system of $10,184 per patient. These results imply that the hydrophilic coated catheter was associated with both health benefits and substantial cost-savings compared to the non-coated catheter. For this reason, it is proposed that hydrophilic coated catheters should be the first and standard choice for those who are prescribed intermittent catheterization.

Lamin E, Newman DK. *Int Urol Nephrol Int Urol Nephrol.* 2016;48(6):931-9[41]
Clean intermittent catheterization revisited.
Review summarizing important features related to successful intermittent catheterization. It highlights the importance of infection prevention among catheter users and identifies hydrophilic-coated catheters as a cost-effective contributor. It acknowledges that hydrophilic catheters may vary in the quality of coatings and LoFric and the Urotonic™ Surface Technology are described.

Clark JF, Mealing SJ, Scott DA, Vogel LC, Krassioukov A, Spinelli M, Bagi P, Wyndaele JJ. *Spinal Cord.* 2016;54(1):73-7.[24]
A cost-effectiveness analysis of long-term intermittent catheterisation with hydrophilic and uncoated catheters.
Health economy evaluation concluding that hydrophilic-coated catheters are cost-effective as they are associated with lower number of UTI events, higher life-expectancy, and better quality of life as compared to non-coated catheters.

Bermingham SL, Hodgkinson S, Wright S, Hayter E, Spinks J, Pellowe C. *BMJ.* 2013;346:e8639[23]
Intermittent self catheterisation with hydrophilic, gel reservoir, and non-coated catheters: a systematic review and cost effectiveness analysis.
Cost-effectiveness and meta-analysis based on two randomized controlled trials with hydrophilic catheters, whereof one with LoFric. The results propose a 20% risk reduction for UTI with hydrophilic-coated compared to non-hydrophilic catheters but does not support cost-effectiveness due to the lack of evidence. The clinical recommendation is that patients should be offered a choice between hydrophilic and gel reservoir catheters.

"The use of [hydrophilic-coated] HC catheters for intermittent catheterisation in SCI patients is highly cost effective. The outcome is consistent irrespective of whether UTI data are collected in hospital or community settings ..."[24]

ENVIRONMENTAL IMPACT

At Wellspect HealthCare we take our environmental responsibility seriously. We continuously work to minimize the environmental impact related to our products. We ensure that proper materials are used and all applicable production requirements are followed. For the LoFric catheter, this means that we use a core catheter material with proven low environmental impact as compared to other common catheter materials[107] without compromising quality and patient perception.[108,109] In fact, the core material of LoFric has been proven to optimize catheter management and reduce discomfort.[108]

LoFric documentation: Environmental impact of material

Johansson K, Greis G, Johansson B, Grundtmann A, Pahlby Y, Torn S, Axelberg H, Carlsson P. *Scand J Urol.* 2013;47(1):33-7[108]

Evaluation of a new PVC-free catheter material for intermittent catheterization: a prospective, randomized, crossover study.

Study of 104 LoFric users who tested two types of LoFric with different core material for 1 week each. Results showed unchanged perception and safety as well as low percieved discomfort with both materials.

This randomized cross-over study compared two types of LoFric catheters with a core material made either by polyvinylchloride (PVC) or a PVC-free material. The study followed 104 male LoFric-users who had maintained urethral sensibility and who evaluated discomfort (e.g pain, burning sensation, bleeding or other discomfort) associated with the catheterization procedure after one week's use. Catheter material properties such as stiffness and flexibility were also evaluated along with general catheter management properties. Self-reported patient questionnaires were used and the results showed that among all patients 38% perceived discomfort during catheterization on a general basis. Patient preferences were different and varied between the two catheter types. For example, 10% experienced discomfort with both catheter types, 5% reported discomfort with the PVC-free and not with the PVC catheter and 19% reported discomfort with the PVC and not the PVC-free catheter (p=0.0066). Even though both catheter types were associated with low predefined discomfort rates and good management properties, the PVC-free material was reported as the better choice to optimize patient satisfaction and tolerablility.

Witjes JA, Del Popolo G, Marberger M, Jonsson O, Kaps HP, Chapple CR. *J Urol.* 2009;182(6):2794-8[109]

A multicenter, double-blind, randomized, parallel group study comparing polyvinyl chloride and polyvinyl chloride-free catheter materials.

Study of 169 LoFric users who tested two types of LoFric catheters with different core material for one month each. Results showed similar perception and safety for both materials.

Stripple H, Westman R, Holm D. *J Clean Prod.* 2008;16(16):1764–76[107]

Development and environmental improvements of plastics for hydrophilic catheters in medical care: an environmental evaluation.

Material life cycle assessment of LoFric and other hydrophilic catheters' core materials. Results show minimized environmental impact for LoFric.

MISCELLANEOUS

With more than 30 years on the market, LoFric has been used and documented in several ways. In addition to efficiently emptying the bladder, LoFric's versatile use includes treatment and prevention of recurrent strictures,[79,92,94,95,97] administration of chemotherapy by bladder instillation,[99,100] and resolution of rare complications.[110] For example, Montagnino describes general use of LoFric to facilitate and prevent surgical procedures of the urethra and bladder.[86] Intermittent catheterization with LoFric has also been shown to have an impact on renal recovery. For example, Halleberg Nyman et al. show faster return of normal bladder function after surgery[111] and Petterson-Hammerstad et al. describe improved renal function in favor of intermittent catheterization with LoFric as compared to indwelling catheterization.[112]

LoFric documentation: Other

Halleberg Nyman M, Gustafsson M, Langius-Eklof A, Johansson JE, Norlin R, Hagberg L. *Int J Nurs Stud.* 2013;50(12):1589-98[111]

Intermittent versus indwelling urinary catheterisation in hip surgery patients: a randomised controlled trial with cost-effectiveness analysis.

Study of 170 hip surgery patients showing evidence of faster return of normal bladder function after surgery when practicing intermittent catheterization with LoFric compared to using indwelling catheters.

This randomized controlled trial of 170 hip surgeries compared routine use of an indwelling catheter inserted in the morning of the day of the surgery to the use of intermittent catheterization when indicated after bladder scan measurements. Intermittent catheterization with LoFric was done if the patient was unable to void and if the bladder scan indicated more than 400ml of urine in the bladder. The study investigated post-surgery follow-up after 4 months, quality of life assessments using EQ-5D and SF-36 (SF-6D), and cost-effectiveness based on quality adjusted life years (QALYs). The results show no statistically significant difference in UTI rate between the groups although there were fewer events reported in the intermittent group. Use of intermittent catheterization was associated with faster return to normal voiding. Normal bladder function was defined as post-voiding residual volume of 150ml or less detected by bladder scan. No differences in cost-effectiveness could be concluded from the results. The authors noted that their infection rates were reduced compared to earlier studies; from 52% in 2011 to 11% in 2013 and that this was likely related to increased use of antibiotic prophylaxis (Cloxacillin) and increased awareness of basic hygiene.

Table based on results reported by Halleberg Nyman et al. 2013[11]

	Intermittent	Indwelling
Number of nosocomial UTI	8 (9%)	10 (12%)
Time to normal bladder function	24 (13-48) hours	48 (43-55)* hours
Number of bladder scans	6 (4-9)	2 (1-3)*
Total costs (SD)	€3642 (1605)	€3954 (1743)

*p-value <0.05
SD = Standard Deviation

Pettersson-Hammerstad K, Jonsson O, Svennung IB, Karlsson AK. *J Urol.* 2008;180(1):187-91[112]

Impaired renal function in newly spinal cord injured patients improves in the chronic state-effect of clean intermittent catheterization?

Observational 3-5 years follow-up of 169 spinal cord injured patients, using either LoFric intermittent catheters or indwelling catheters. The results showed better renal function improvement related to intermittent catheterization use.

"Renal function improves with time after injury and improvement is seen most clearly in the group that uses clean intermittent catheterization as a bladder emptying method."[112]

Mistry S, Goldfarb D, Roth DR. *Urology.* 2007;70(1):25-7[113]

Use of hydrophilic-coated urethral catheters in management of acute urinary retention.

An example of LoFric use to treat acute urinary retention.

"... the hydrophilic catheter should be a part of the urologist's armamentarium whenever treating men with acute urinary retention."[113]

Vaidyanathan S, Krishnan KR, Soni BM, Fraser MH. *Spinal Cord.* 1996;34(12):745-7[110]

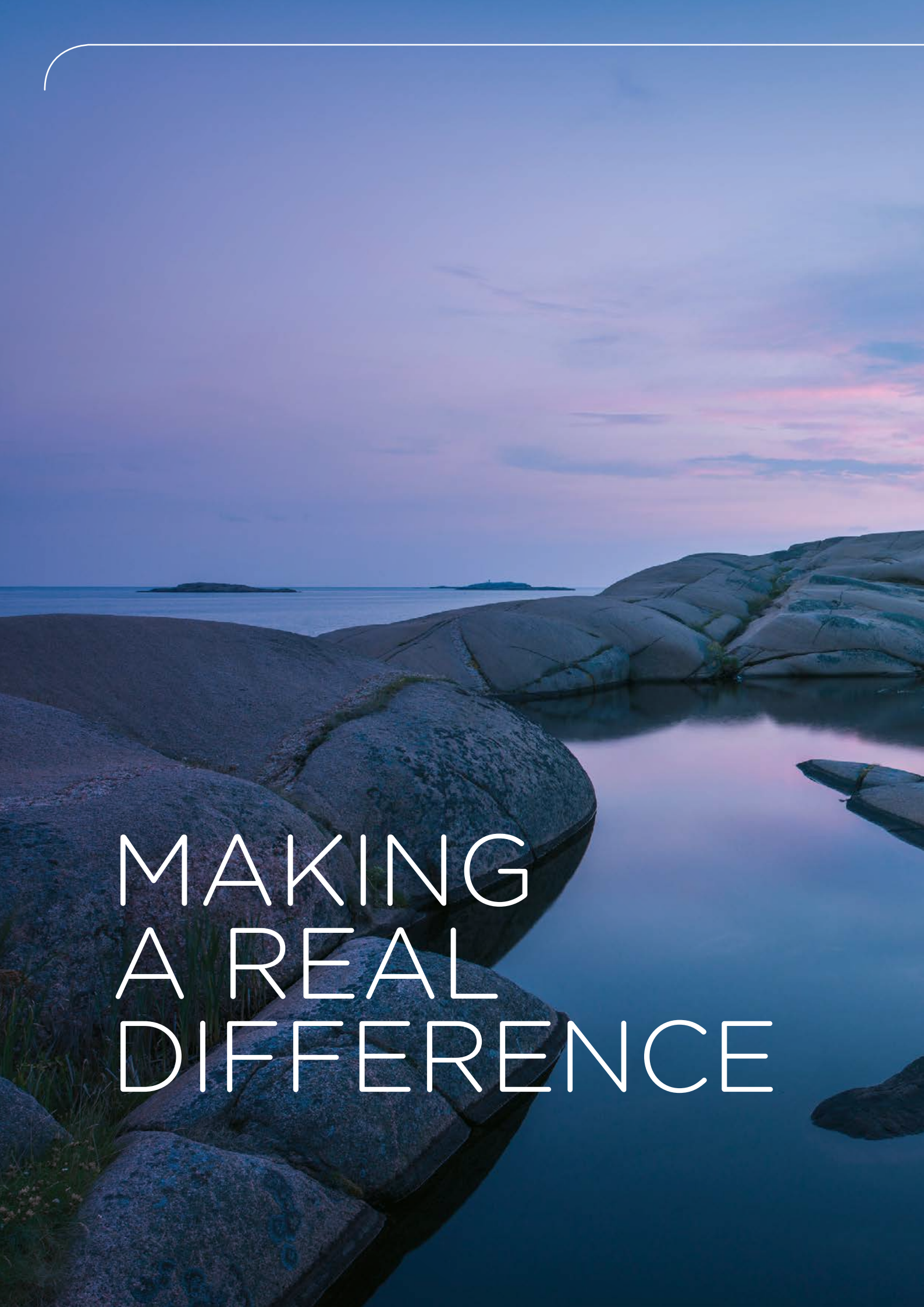
Unusual complications of intermittent self-catheterisation in spinal cord injury patients.

Case report on three rare events solved by LoFric use.

Bakke A, Brun OH, Hoisaeter PA. *Scand J Urol Nephrol.* 1992;26(3):211-7[114]

Clinical background of patients treated with clean intermittent catheterization in Norway.

Observational 13-month study of 302 users (95% LoFric) providing epidemiological data on the use of intermittent catheterization for persons with different disabilities.



MAKING A REAL DIFFERENCE

Wellspect®
A REAL DIFFERENCE

SUMMARY OF LOFRIC CLINICAL EVIDENCE

× Publication/study of general importance
× × Publication/study of significant importance

Author	Year	Long-term safety	UTI	Trauma	Friction	Preference	Dilatation	Instillation	Environmental	Other
Koeter et al.[76]	2018					×				
Welk et al.[105]	2018		×							×
Truzzi et al.[103]	2018		×							×
Watanabe et al.[104]	2017		×							×
DeFoor et al.[40]	2017		× ×							
Rognoni and Tarricone[53,102]	2017		×							×
Rognoni and Tarricone[26,53]	2017		×	×						
Håkansson et al.[106]	2016		×	×						×
Lamin and Newman et al.[41]	2016		× ×	×	×					
Lucas et al.[42]	2016		×							
Clark et al.[24]	2015		× ×							×
Håkansson et al.[19]	2015	×	×							
Wilson[77]	2015					×				
Prieto et al.[22,27,43]	2014		× ×							
Li et al.[25]	2013		× ×	× ×						
Bermingham et al.[23]	2013									×
Woodward[78]	2013					×				
Rijal et al.[92]	2013						× ×			
Johansson et al.[108]	2013					×			× ×	
Halleberg Nyman et al.[111]	2013									× ×
Sallami et al.[79]	2011					× ×	× ×			
Cardenas and Hoffman[28]	2009		×							
Lauritzen et al.[93]	2009						× ×			
Witjes et al.[109]	2009					×			×	
Pettersson-Hammarstad et al.[112]	2008									× ×
Taskinen et al.[80]	2008					×				
Stripple et al.[107]	2008								× ×	
Bjerklund Johansen et al.[81]	2007					×				
Litherland and Schiotz[82]	2007					×				
Mistry et al.[113]	2007									×
Stensballe et al.[55]	2005			× ×	×					
Dell and Parsons[99]	2004							× ×		
Vapnek et al.[33]	2003		×	× ×						
Saad et al.[100]	2002							× ×		
Fader et al.[82]	2001					×				
Lopez Pereira et al.[74]	2001					× ×				

× Publication/study of general importance
× × Publication/study of significant importance

Author	Year	Long-term safety	UTI	Trauma	Friction	Preference	Dilatation	Instillation	Environmental	Other
Pascoe and Clovis[84]	2001					×				
Hedlund et al.[21]	2001				× ×					
Jones et al.[62]	2001					×				
Mauroy et al.[85]	2001					×				
Lundgren et al.[59]	2000					×				
Montagnino[86]	2000					×				
Pachler and Frimodt-Møller[87]	1999				×	×	×			
Waller et al.[58]	1997					× ×				
Bakke et al.[17]	1997		× ×		×					
Sutherland et al.[44]	1996				× ×		× ×			
Vaidyanathan et al.[110]	1996									×
Diokno et al.[73]	1995						× ×			
Waller et al.[18]	1995		× ×		×					
Vaidyanathan et al.[56]	1994				× ×					
Harris et al.[94]	1994						× ×			
Kjaergaard et al.[95]	1994						× ×			
Bakke and Vollset[45]	1993			×						
Bakke et al.[46]	1993			× ×						
Bodker et al.[96]	1992						×			
Bakke et al.[114]	1992									×
Bakke and Digranes[47]	1991			×						
Hellstrom et al.[57]	1991				×					
Robertson et al.[97]	1991						×			
Lawrence and MacDonagh[98]	1988						×			

REFERENCES

1. Wyndaele JJ. Intermittent catheterization: which is the optimal technique? Spinal Cord. Sep 2002;40(9):432-437.

2. Whiteside SA, Razvi H, Dave S, Reid G, Burton JP. The microbiome of the urinary tract-a role beyond infection. Nat Rev Urol. Feb 2015;12(2):81-90.

3. Lapides J, Diokno AC, Silber SJ, Lowe BS. Clean, intermittent self-catheterization in the treatment of urinary tract disease. J Urol. Mar 1972;107(3):458-461.

4. Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA. Guideline for prevention of catheter-associated urinary tract infections 2009. Infect Control Hosp Epidemiol. Apr 2010;31(4):319-326.

5. Hooton TM, Bradley SF, Cardenas DD, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 international clinical practice guidelines from the Infectious Disease Society of America. Clin Infect Dis. Mar 1 2010;50(5):625-663.

6. Hunter KF, Bharmal A, Moore KN. Long-term bladder drainage: Suprapubic catheter versus other methods: a scoping review. Neurourol Urodyn. Sep 2013;32(7):944-951.

7. Tambyah PA, Oon J. Catheter-associated urinary tract infection. Curr Opin Infect Dis. Aug 2012;25(4):365-370.

8. Tenke P, Kovacs B, Bjerklund Johansen TE, Matsumoto T, Tambyah PA, Naber KG. European and Asian guidelines on management and prevention of catheter-associated urinary tract infections. Int J Antimicrob Agents. Feb 2008;31 Suppl 1:S68-78.

9. Tenke P, Koves B, Johansen TE. An update on prevention and treatment of catheter-associated urinary tract infections. Curr Opin Infect Dis. Feb 2014;27(1):102-107.

10. Katsumi HK, Kalisvaart JF, Ronningen LD, Hovey RM. Urethral versus suprapubic catheter: choosing the best bladder management for male spinal cord injury patients with indwelling catheters. Spinal Cord. Apr 2010;48(4):325-329.

11. Bardsley A. Intermittent Self-Catheterisation in women: reducing the risk of UTIs. urology supplements. 2014;22(18).

12. Le Breton F, Guinet A, Verollet D, Jousse M, Amarenco G. Therapeutic education and intermittent self-catheterization: recommendations for an educational program and a literature review. Ann Phys Rehabil Med. Apr 2012;55(3):201-212.

13. Shaw C, Logan K, Webber I, Broome L, Samuel S. Effect of clean intermittent self-catheterization on quality of life: a qualitative study. J Adv Nurs. Mar 2008;61(6):641-650.

14. Vahr S, Cobussen-Boekhorst H, Eikenboom J, et al. Evidence-based guidline for best practice in urological health care. Catheterisation. Urethral intermittent in adults. Dilatation, urethral intermittent in adults. EAUN guideline. 2013.

15. Wyndaele JJ, Maes D. Clean intermittent self-catheterization: a 12-year followup. J Urol. May 1990;143(5):906-908.

16. Perrouin-Verbe B, Labat JJ, Richard I, Mauduyt de la Greve I, Buzelin JM, Mathe JF. Clean intermittent catheterisation from the acute period in spinal cord injury patients. Long term evaluation of urethral and genital tolerance. Paraplegia. Nov 1995;33(11):619-624.

17. Bakke A, Digranes A, Hoisaeter PA. Physical predictors of infection in patients treated with clean intermittent catheterization: 7-year study. Br J Urol. Jan 1997;79(1):85-90.

18. Waller L, Jonsson O, Norlen L, Sullivan L. Clean intermittent catheterization in spinal cord injury patients: long-term followup of a hydrophilic low friction technique. J Urol. Feb 1995;153(2):345-348.

19. Hakansson MA, Neovius K, Norrback M, Svensson J, Lundqvist T. Health Care Utilization and Complications Rates among Users Of Hydrophilic-Coated Catheters. Urol Nurs. Sep-Oct 2015;35(5):239-247.

20. Chartier-Kastler E, Denys P. Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention. Neurourol Urodyn. Jan 2011;30(1):21-31.

21. Hedlund H, Hjelmas K, Jonsson O, Klarskov P, Talja M. Hydrophilic versus non-coated catheters for intermittent catheterization. Scand J Urol Nephrol. Feb 2001;35(1):49-53.

22. Prieto J, Murphy CL, Moore KN, Fader M. Intermittent catheterisation for long-term bladder management. Cochrane Database Syst Rev. Sep 10 2014;9:CD006008.

23. Bermingham SL, Hodgkinson S, Wright S, Hayter E, Spinks J, Pellowe C. Intermittent self catheterisation with hydrophilic, gel reservoir, and non-coated catheters: a systematic review and cost effectiveness analysis. BMJ. 2013;346:e8639.

24. Clark JF, Mealing SJ, Scott DA, et al. A cost-effectiveness analysis of long-term intermittent catheterisation with hydrophilic and uncoated catheters. Spinal Cord. Jul 21 2015;54(1):73-77.

25. Li L, Ye W, Ruan H, Yang B, Zhang S. Impact of hydrophilic catheters on urinary tract infections in people with spinal cord injury: systematic review and meta-analysis of randomized controlled trials. Arch Phys Med Rehabil. Apr 2013;94(4):782-787.

26. Rognoni C, Tarricone R. Intermittent catheterisation with hydrophilic and non-hydrophilic urinary catheters: systematic literature review and meta-analyses. BMC Urol. Jan 10 2017;17(1):4.

27. Prieto J, Murphy CL, Moore KN, Fader M. Erratum. Intermittent catheterisation: Which catheter designs, techniques and strategies affect the incidence of UTI, other complications and user acceptability? A Cochrane systematic review. Neurourology and Urodynamics. 2015;34(8):802-802.

28. Cardenas DD, Hoffman JM. Hydrophilic catheters versus noncoated catheters for reducing the incidence of urinary tract infections: a randomized controlled trial. Arch Phys Med Rehabil. Oct 2009;90(10):1668-1671.

29. Cardenas DD, Moore KN, Dannels-McClure A, et al. Intermittent catheterization with a hydrophilic-coated catheter delays urinary tract infections in acute spinal cord injury: a prospective, randomized, multicenter trial. PM R. May 2011;3(5):408-417.30. De

Ridder DJ, Everaert K, Fernandez LG, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: A prospective randomised parallel comparative trial. Eur Urol. Dec 2005;48(6):991-995.

31. Ercole FF, Macieira TG, Wenceslau LC, Martins AR, Campos CC, Chianca TC. Integrative review: evidences on the practice of intermittent/indwelling urinary catheterization. Rev Lat Am Enfermagem. Feb 2013;21(1):459-468.

32. Hill TC, Baverstock R, Carlson KV, et al. Best practices for the treatment and prevention of urinary tract infection in the spinal cord injured population: The Alberta context. Can Urol Assoc J. Mar-Apr 2013;7(3-4):122-130.

33. Vapnek JM, Maynard FM, Kim J. A prospective randomized trial of the LoFric hydrophilic coated catheter versus conventional plastic catheter for clean intermittent catheterization. J Urol. Mar 2003;169(3):994-998.

34. Woodbury MG, Hayes KC, Askes HK. Intermittent catheterization practices following spinal cord injury: a national survey. Can J Urol. Jun 2008;15(3):4065-4071.

35. Moore KN, Fader M, Getliffe K. Long-term bladder management by intermittent catheterisation in adults and children. Cochrane Database Syst Rev. 2007(4):CD006008.

36. Getliffe K, Fader M, Allen C, Pinar K, Moore KN. Current evidence on intermittent catheterization: sterile single-use catheters or clean reused catheters and the incidence of UTI. J Wound Ostomy Continence Nurs. May-Jun 2007;34(3):289-296.

37. Wyndaele JJ, Brauner A, Geerlings SE, Bela K, Peter T, Bjerklund-Johanson TE. Clean intermittent catheterization and urinary tract infection: review and guide for future research. BJU Int. Dec 2012;110(11 Pt C):E910-917.

38. Hakansson MA. Reuse versus single-use catheters for intermittent catheterization: what is safe and preferred? Review of current status. Spinal Cord. Jul 2014;52(7):511-516.

39. Goetz LL, Cardenas DD, Kennelly M, et al. International Spinal Cord Injury Urinary Tract Infection Basic Data Set. Spinal Cord. Sep 2013;51(9):700-704.

40. DeFoor W, Reddy P, Reed M, et al. Results of a prospective randomized control trial comparing hydrophilic to uncoated catheters in children with neurogenic bladder. Journal of Pediatric Urology. 2017.

41. Lamin E, Newman DK. Clean intermittent catheterization revisited. Int Urol Nephrol. Mar 8 2016;48(6):931-939.

42. Lucas EJ, Baxter C, Singh C, et al. Comparison of the microbiological milieu of patients randomized to either hydrophilic or conventional PVC catheters for clean intermittent catheterization. J Pediatr Urol. Feb 18 2016;12(3):172.e171-178.

43. Prieto JA, Murphy C, Moore KN, Fader MJ. Intermittent catheterisation for long-term bladder management (abridged Cochrane Review). Neurourol Urodyn. Jun 5 2015;34(7):648-653.

44. Sutherland RS, Kogan BA, Baskin LS, Mevorach RA. Clean intermittent catheterization in boys using t he LoFric catheter. J Urol. Dec 1996;156(6):2041-2043.

45. Bakke A, Vollset SE. Risk factors for bacteriuria and clinical urinary tract infection in patients treated with clean intermittent catheterization. J Urol. Mar 1993;149(3):527-531.

46. Bakke A, Vollset SE, Hoisaeter PA, Irgens LM. Physical complications in patients treated with clean intermittent catheterization. Scand J Urol Nephrol. 1993;27(1):55-61.

47. Bakke A, Digranes A. Bacteriuria in patients treated with clean intermittent catheterization. Scand J Infect Dis. 1991;23(5):577-582.

48. Newman DK, Willson MM. Review of intermittent catheterization and current best practices. Urol Nurs. Jan-Feb 2011;31(1):12-28, 48; quiz 29.

49. NICE, Guideline. Healthcare-associated infections: prevention and control in primary and community care. Clinical guideline [CG139]. Royal College of Physicians National Institute for Health and Clinical Excellence. 2012.

50. Elvy J, Colville A. Catheter associated urinary tract infection: what is it, what causes it and how can we prevent it? Journal of Infection Prevention. 2009;10(2).

51. Heard L, Buhrer R. How do we prevent UTI in people who perform intermittent catheterization? Rehabil Nurs. Mar-Apr 2005;30(2):44-45, 61.

52. Bennett E. Intermittent self-catheterisation and the female patient. Nurs Stand. Oct 30-Nov 5 2002;17(7):37-42.

53. Rognoni C, Tarricone R. Clinical and economic evaluation of LoFric® catheters for the management of bladder dysfunctions. Bocconi University, Milan, Italy: CERGAS Center for Research for Healthcare and Social Management;2016.

54. Bolinger R, Engberg S. Barriers, complications, adherence, and self-reported quality of life for people using clean intermittent catheterization. J Wound Ostomy Continence Nurs. Jan-Feb 2013;40(1):83-89.

55. Stensballe J, Looms D, Nielsen PN, Tvede M. Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma:... Eur Urol. Dec 2005;48(6):978-983.

56. Vaidyanathan S, Soni BM, Dundas S, Krishnan KR. Urethral cytology in spinal cord injury patients performing intermittent catheterisation. Paraplegia. Jul 1994;32(7):493-500.

57. Hellstrom P, Tammela T, Lukkarinen O, Kontturi M. Efficacy and safety of clean intermittent catheterization in adults. Eur Urol. 1991;20(2):117-121.

58. Waller L, Telander M, Sullivan L. The importance of osmolality in hydrophilic urethral catheters: a crossover study. Spinal Cord. Apr 1997;35(4):229-233.

59. Lundgren J, Bengtsson O, Israelsson A, Jonsson AC, Lindh AS, Utas J. The importance of osmolality for intermittent catheterization of the urethra. Spinal Cord. Jan 2000;38(1):45-50.

60. Dunger DB, Seckl JR, Grant DB, Yeoman L, Lightman SL. A short water deprivation test incorporating urinary arginine vasopressin estimations for the investigation of posterior pituitary function in children. Acta Endocrinol (Copenh). Jan 1988;117(1):13-18.

61. Tibblin G, Vikgren P. Urine Osmolality in a Population Study of Hypertension. Bull World Health Organ. 1964;31:345-348.

62. Jones DS, Garvin CP, Gorman SP. Design of a simulated urethra model for the quantitative assessment of urinary catheter lubricity. J Mater Sci Mater Med. Jan 2001;12(1):15-21.

63. Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research. A comprehensive review. J Clin Pharm Ther. Oct 2001;26(5):331-342.

64. Morris LS, Schulz RM. Medication compliance: the patient's perspective. Clin Ther. May-Jun 1993;15(3):593-606.

65. Wilde MH, Brasch J, Zhang Y. A qualitative descriptive study of self-management issues in people with long-term intermittent urinary catheters. J Adv Nurs. Jun 2011;67(6):1254-1263.

66. Chick HE, Hunter KF, Moore KN. Parent and child experiences using a hydrophilic or reused PVC catheter for intermittent catheterisation. J Clin Nurs. Feb 2013;22(3-4):513-520.

67. Kelly L, Spencer S, Barrett G. Using intermittent self-catheters: experiences of people with neurological damage to their spinal cord. Disabil Rehabil. Apr 25 2014;36(3):220-226.

68. Woodward S. Dos and don'ts of intermittent self-catheterisation. Br J Nurs. Oct 10-23 2013;22(18):S10.

69. Cobussen-Boekhorst H, Hermeling E, Heesakkers J, van Gaal B. Patients' experience with intermittent catheterisation in everyday life. J Clin Nurs. Mar 16 2016;25 (9-10):1253-1261.

70. Seth JH, Haslam C, Panicker JN. Ensuring patient adherence to clean intermittent self-catheterization. Patient Prefer Adherence. 2014;8:191-198.

71. Neovius KE, Lundqvist T. CIC users' preference for catheters reducing the UTI frequency. Value in Health 2014;17(7).

72. Pinder B, Lloyd AJ, Nafees B, Elkin EP, Marley J. Patient preferences and willingness to pay for innovations in intermittent self-catheters. Patient Prefer Adherence. 2015;9:381-388.

73. Diokno AC, Mitchell BA, Nash AJ, Kimbrough JA. Patient satisfaction and the LoFric catheter for clean intermittent catheterization. J Urol. Feb 1995;153(2):349-351.

74. Lopez Pereira P, Martinez Urrutia MJ, Lobato L, Rivas S, Jaureguizar Monereo E. [Comparative study of the degree of patient satisfaction in intermittent catheterization with Lofric and polyvinyl chloride catheters]. Actas Urol Esp. Nov-Dec 2001;25(10):725-730.

75. Moore KC, Lester M, Robinson E, Bagulay N, Pearce I. Cleaning and re-using intermittent self catheters: a questionnaire to gauge patient's perceptions and prejudices. Journal of Clinical Urology. 2014;7(4):277-282.

76. Koeter I, Stensröd G, Hunsbedt Nilsen A, et al. User perception of a new hydrophilic-coated male urinary catheter for intermittent use. Nursing Open. 2018;0(0)

77. Wilson M. Clean intermittent self-catheterisation: working with patients. Br J Nurs. Jan 22 2015;24(2):76-85.

78. Woodward S. Improving quality of life for men using intermittent self-catheterisation. British journal of neuroscience nursing. 2013;9(3):114-119.

79. Sallami S, Mouine Y, Rhouma SB, Cherif K, Dahmani A, Horchani A. Clean Intermittent Catheterization Following Urethral Stricture Surgery Using a Low Friction Catheter Versus Conventional Plastic Catheter: A Prospective, Randomized Trial. UroToday International Journal 2011;4(1).

80. Taskinen S, Fagerholm R, Ruutu M. Patient experience with hydrophilic catheters used in clean intermittent catheterization. J Pediatr Urol. Oct 2008;4(5):367-371.

81. Bjerklund Johansen T, Hultling C, Madersbacher H, Del Popolo G, Amarenco G, LoFric Primo Study G. A novel product for intermittent catheterisation: its impact on compliance with daily life – international multicentre study. Eur Urol. Jul 2007;52(1):213-220.

82. Litherland AT, Schiotz HA. Patient-perceived discomfort with two coated urinary catheters. Br J Nurs. Mar 8-21 2007;16(5):284-287.

83. Fader M, Moore KN, Cottenden AM, Pettersson L, Brooks R, Malone-Lee J. Coated catheters for intermittent catheterization: smooth or sticky? BJU Int. Sep 2001;88(4):373-377.

84. Pascoe G, Clovis S. Evaluation of two coated catheters in intermittent self-catheterization. Br J Nurs. Mar 8-21 2001;10(5):325-329.

85. Mauroy B, Soret R, Bonnal JL, Fantoni JC. [Comparison of 3 self lubrificated urethral catheters: prospective study on 27 patients]. Ann Urol (Paris). Jul 2001;35(4):223-228.

86. Montagnino B. The LoFric catheter: new technology improves an old technique. Urol Nurs. Aug 2000;20(4):247-249, 253.

87. Pachler J, Frimodt-Moller C. A comparison of prelubricated hydrophilic and non-hydrophilic polyvinyl chloride catheters for urethral catheterization. BJU Int. May 1999;83(7):767-769.

88. Wessells H, Angermeier KW, Elliott S, et al. Male Urethral Stricture: American Urological Association Guideline. J Urol. Jan 2017;197(1):182-190.

89. Wyndaele JJ. Complications of intermittent catheterization: their prevention and treatment. Spinal Cord. Oct 2002;40(10):536-541.

90. Elhaj Z, Ibrahim A, Sharfi. The Role Clean Self Intermittent Catheterization Following Direct Vision Internal Urethrotomy in Reduction of Recurrence of Urethral Stricture. Global Journal of Medical research Diseases. 2013;13 (5).

91. Lubahn JD, Zhao LC, Scott JF, et al. Poor quality of life in patients with urethral stricture treated with intermittent self-dilation. J Urol. Jan 2014;191(1):143-147.

92. Rijal A, Little B, McPhee S, Meddings RN. Bladder outflow problems in females. Nepal Med Coll J. Mar 2013;15(1):46-49.

93. Lauritzen M, Greis G, Sandberg A, Wedren H, Ojdeby G, Henningsohn L. Intermittent self-dilatation after internal urethrotomy for primary urethral strictures: a case-control study. Scand J Urol Nephrol. 2009;43(3):220-225.

94. Harriss DR, Beckingham IJ, Lemberger RJ, Lawrence WT. Long-term results of intermittent low-friction self-catheterization in patients with recurrent urethral strictures. Br J Urol. Dec 1994;74(6):790-792.

95. Kjaergaard B, Walter S, Bartholin J, et al. Prevention of urethral stricture recurrence using clean intermittent self-catheterization. Br J Urol. Jun 1994;73(6):692-695.

96. Bodker A, Ostri P, Rye-Andersen J, Edvardsen L, Struckmann J. Treatment of recurrent urethral stricture by internal urethrotomy and intermittent self-catheterization: a controlled study of a new therapy. J Urol. Aug 1992;148(2 Pt 1):308-310.

97. Robertson GS, Everitt N, Lamprecht JR, Brett M, Flynn JT. Treatment of recurrent urethral strictures using clean intermittent self-catheterisation. Br J Urol. Jul 1991;68(1):89-92.

98. Lawrence WT, MacDonagh RP. Treatment of urethral stricture disease by internal urethrotomy followed by intermittent 'low-friction' self-catheterization: preliminary communication. J R Soc Med. Mar 1988;81(3):136-139.

99. Dell JR, Parsons CL. Multimodal therapy for interstitial cystitis. J Reprod Med. Mar 2004;49(3 Suppl):243-252.

100. Saad A, Oakes G, Thompson AC, et al. Delaying the Administration of Intravesical Chemotherapy Improves its Dwell Time. UroOncology. 2002;2(1):23-26.

101. Neovius K, Åberg-Håkansson M, Lundqvist T. Health economic evaluation of hydrophilic coated versus non-coated urinary catheters for intermittent use in The United States. Value in Health. 2016;19(3):A310.

102. Rognoni C, Tarricone R. Healthcare resource consumption for intermittent urinary catheterisation: cost-effectiveness of hydrophilic catheters and budget impact analyses. BMJ Open. Jan 17 2017;7(1):e012360.

103. Truzzi JC, Teich V, Pepe C. Can hydrophilic coated catheters be beneficial for the public healthcare system in Brazil? – A cost-effectiveness analysis in patients with spinal cord injuries. Int Braz J Urol. 2018;44(1):121-131.

104. Watanabe T, Yamamoto S, Gotoh M, et al. Cost-Effectiveness Analysis of Long-Term Intermittent Self-Catheterization with Hydrophilic-Coated and Uncoated Catheters in Patients with Spinal Cord Injury in Japan. Low Urin Tract Symptoms. 2017;9(3):142-150.

105. Welk B, Isaranuwatchai W, Krassioukov A, Husted Torp L, Elterman D. Cost-effectiveness of hydrophilic-coated intermittent catheters compared with uncoated catheters in Canada: a public payer perspective. J Med Econ. Mar 15 2018:1-10.

106. Håkansson MA, Neovius K, Lundqvist T. Healthcare Costs Associated to Hydrophilic Coated and Non-Coated Urinary Catheters for Intermittent Use in the United States. Urol Nurs. 2016;36(5):233-242.

107. Stripple H, Westman R, Holm D. Development and environmental improvements of plastics for hydrophilic catheters in medical care: an environmental evaluation. Journal of Cleaner Production. 2008;16.

108. Johansson K, Greis G, Johansson B, et al. Evaluation of a new PVC-free catheter material for intermittent catheterization: a prospective, randomized, crossover study. Scand J Urol. Feb 2013;47(1):33-37.

109. Witjes JA, Del Popolo G, Marberger M, Jonsson O, Kaps HP, Chapple CR. A multicenter, double-blind, randomized, parallel group study comparing Polyvinyl Chloride and Polyvinyl Chloride-Free Catheter Materials. J Urol. Dec 2009;182(6):2794-2798.

110. Vaidyanathan S, Krishnan KR, Soni BM, Fraser MH. Unusual complications of intermittent self-catheterisation in spinal cord injury patients. Spinal Cord. Dec 1996;34(12):745-747.

111. Halleberg Nyman M, Gustafsson M, Langius-Eklof A, Johansson JE, Norlin R, Hagberg L. Intermittent versus indwelling urinary catheterisation in hip surgery patients: a randomised controlled trial with cost-effectiveness analysis. Int J Nurs Stud. Dec 2013;50(12):1589-1598.

112. Pettersson-Hammerstad K, Jonsson O, Svennung IB, Karlsson AK. Impaired renal function in newly spinal cord injured patients improves in the chronic state effect of clean intermittent catheterization? J Urol. Jul 2008;180(1):187-191; discussion 191.

113. Mistry S, Goldfarb D, Roth DR. Use of hydrophilic-coated urethral catheters in management of acute urinary retention. Urology. Jul 2007;70(1):25-27.

114. Bakke A, Brun OH, Hoisaeter PA. Clinical background of patients treated with clean intermittent catheterization in Norway. Scand J Urol Nephrol. 1992;26(3):211-217.

Wellspect®
A REAL DIFFERENCE

At Wellspect we value the people behind our success as a leading provider of life-changing products for bowel and bladder management such as the well-known brands LoFric® and Navina™. From the thousands of users and healthcare professionals worldwide who inspire our innovative solutions, we know that working together is the best way to advance continence care, giving our users more time for life. Building on over 30 years of life-improving performance, we passionately strive to make a difference every day to everyone who needs our products and services.

Wellspect. A Real Difference.

wellspect.com

Wellspect HealthCare, Aminogatan 1, P.O. Box 14, SE-431 21 Mölndal, Sweden. Phone: +46 31 376 40 00.