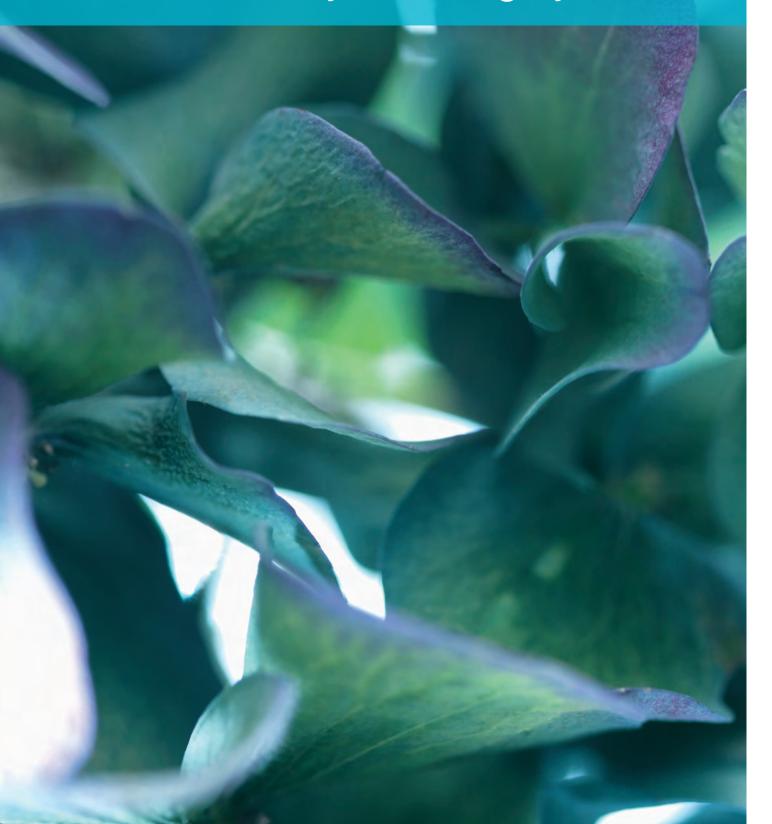
Male Incontinence: Benefits of the Conveen® Urinary Collecting System





Male Incontinence: Benefits of the Conveen® Urinary Collecting System Product Monograph

Table of Contents

Exe	eci	utive	sur	mmary	1
1.	1	Mana	agei	ment of male urinary incontinence	2
	1.1	1 T	уре	s of urinary incontinence	3
	1.2	2 (Caus	ses of male urinary incontinence	3
	1.3	3 Ir	mpa	act of male urinary incontinence	4
	1.4	4 (Cont	tinence products for men	4
	1.5	5 L	Jrina	ary sheaths for male urinary incontinence	5
2.	(Choo	osin	g urinary collecting systems	6
	2	1 1	/lan	aging incontinence can impact quality of life	7
	2.2	2 E	Evide	ence-based guidelines support urinary collecting systems	8
3.	(Cons	side	rations when choosing collecting devices	9
,	3	1 (Cho	osing a urinary sheath	10
	(3.1.1		Benefits of a non-invasive procedure	10
	(3.1.2	2	Importance of correct assessment and fitting	10
	(3.1.3	3	Quality of urinary sheath underpins success	10
	(3.1.4	1	Latex and non-latex urinary sheaths	12
,	3.2	2 (Cho	osing a urine collecting bag	12
	(3.2.1		Sterile versus non-sterile collecting systems	12
	(3.2.1	1.1	Choice of collecting bag with urinary sheaths	12
	3.2.1.2		1.2	Choice of collecting bag with urinary catheters	12
	3.2.2		2	Anti-kink design for unobstructed flow	13
4.	[Envir	onn	nental considerations – choosing the right materials	14
5.	1	Key 1	feat	ures of the Conveen family of urinary collecting devices	16
6.	(Colo	plas	st services	20
Re	fer	ence	es		21
Ар	ре	ndic	es		23
	Fitting guide to Conveen urinary collecting devices				23
	Patient testimonials				26



Executive summary

Incontinence can affect males of all ages, encompassing children with special needs or disabilities (such as spina bifida), independent working-age adults, and elderly nursing home patients with significant comorbidities, where prevalence can exceed 50%.1 Left unmanaged. incontinence can have a major impact on an individual's well-being, leading to diminished quality of life.² Indeed, many men with urinary incontinence experience feelings of embarrassment, loss of selfesteem and humiliation, and are at increased risk of becoming anxious and depressed.² Because urinary incontinence is generally seen as a taboo subject, not surprisingly, many men fail to seek professional help. This lack of communication can be a major barrier to starting successful symptom management or treatment and cause men to 'make-do' with ineffective incontinence products.

Healthcare professionals have a vital role to play in helping incontinent male patients to stay dry and in so doing help restore their patient's sense of well-being. Disposable absorbent products such as incontinence pads and adult diapers are often prescribed as the simplest solution to male incontinence, although evidence suggests that men dislike pads to the extent that those with mild-to-moderate incontinence will adjust their daily routine to use a toilet in preference to pads.³ Moreover, pads are often bulky to wear and have to be changed frequently to reduce the risk of leakage, odour and skin irritation. For men of working age, disposal of bulky pads can be a further source of embarrassment.

Urinary sheaths offer an appealing alternative to traditional incontinence pads and diapers for men with urinary incontinence. Worn over the penis and connected, via a funnel, to a urine collecting bag, they provide a complete solution to male urinary

incontinence. Findings from a clinical study show that they provide a highly reliable solution to the problem of urinary incontinence and are preferred by a majority of men to incontinence pads.⁴ This view has been endorsed by the European Association of Urology (EAU) Working Panel on Urinary Incontinence, which in its latest guidance recommends urinary sheaths for men with urinary incontinence without significant residual urine providing they can be applied easily and independently.⁵

Coloplast's continence care portfolio includes the Conveen® urinary collecting system that encompasses a range of urisheaths and urine collecting bags for discreet, all-day protection. Patients have a range of urisheaths to choose from that are available in different sizes and different lengths; some also contain a balanced self-adhesive for easy application. Results from clinical trials illustrate that the properties of the urisheath are important for individual patients, impacting on patient preference. Coloplast's most advanced, high-performance urisheath is made from skin-friendly breathable silicone material and incorporates anti-leakage features, such as an anti-kink bellow, that guards against blockage.

As this monograph on the Conveen urinary collecting system illustrates, urinary incontinence is a common problem among men, especially as they grow older. Coloplast is committed to providing optimum solutions to continence care. In this monograph specially designed for healthcare professionals, we describe how the Conveen urinary collecting system that encompasses a range of urinary sheaths and bags has been developed to address the twin goals of incontinence care for men – freedom from leakage and preservation of skin health.



Chapter 1

Management of male urinary incontinence

Although there have been both medical and surgical advances in the treatment of incontinence, complete bladder control is not an attainable goal for all men. Many still need access to incontinence products to enable them to stay dry so that they can function normally and have a good quality of life. With an expanding range of continence products, men now have a greater choice than ever before to achieve optimal continence care.

1.1 Types of urinary incontinence

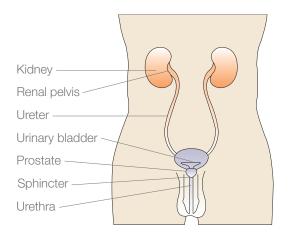
Urinary incontinence (enuresis) is defined as the involuntary or accidental leakage of urine.⁸ It may take one of several forms (Table 1).

Table 1. Common types of urinary incontinence				
Stress urinary incontinence (SUI)	Involuntary loss of urine that arises from actions, such as coughing, sneezing, and lifting that put abdominal pressure on the bladder. SUI occurs when the muscles in the pelvic floor, under sudden, increased pressure (stress), are too weak to hold the urethral sphincters closed			
Urge incontinence (unstable or overactive bladder)	Involuntary loss of urine following an overwhelming urge to urinate that cannot be stopped. Urge incontinence is caused by involuntary, uncontrolled contractions of the muscle in the bladder			
Overflow incontinence	Constant dribbling of urine usually associated with urinating frequently and in small amounts			
Mixed incontinence	Features of both urge and stress incontinence			

1.2. Causes of male urinary incontinence

Urine, produced in the kidneys, flows from the kidneys via the ureters into the bladder (Figure 1), where it is stored until bladder pressure exceeds urethral resistance. The healthy bladder expels urine in a controlled, usually voluntary fashion, about 4–8 times a day. Bladder activity is regulated by the central and peripheral nervous systems – stretch receptors in the bladder tell the brain that the bladder is full and there is a need to pass urine.

Figure 1. The male urinary tract



Incontinence occurs when bladder dysfunction inhibits the urge to pass urine or when normal toileting ability is impaired. This can arise from chronic illness, injury, or immobility as well as from cognitive impairment associated with dementia (Table 2). Incontinence is known to be a precipitating factor for residential care among the elderly population,9 while also being the single most important determinant of institutionalisation among dementia patients. 10 In addition to demographic factors such as advancing age and obesity, there is some evidence to suggest that incontinence may also be precipitated by certain medications that depress detrusor activity leading to urinary retention and overflow incontinence, although data on the link between drugs and incontinence are weak.5

Prostate surgery, such as radical prostatectomy for prostate cancer, is a leading cause of male urinary incontinence, especially SUI.¹¹ Any disease, injury, or condition that affects the coordination of the nerves and muscles of the genitourinary system can also lead to neurogenic bladder (bladder dysfunction associated with neurological disorders) and in turn to urinary incontinence.

	Table 2.	Aetiology	of urinary	, incontinen	ce ⁵
--	----------	------------------	------------	--------------	-----------------

Medical conditions	Benign prostatic hyperplasia			
	Congestive heart failure			
	 Constipation 			
	 Chronic obstructive pulmonary disease 			
	Chronic cough			
	• Diabetes			
	 Dementia and cognitive impairment 			
	 Major pelvic surgery, such as radical prostatectomy 			
	 Sleep disturbances, such as sleep apnoea 			
Demographic factors	Advancing age, especially if accompanied by cognitive impairmentObesity			
Neurogenic bladder	Stroke			
	Parkinson's disease			
	Multiple sclerosis			
	Spinal cord injuries			
	 Neural tube defects, such as spina bifida 			

1.3. Impact of male urinary incontinence

Although urinary incontinence is less common in men than in women and less common in younger than older men, it still affects significant numbers of men worldwide. About 1 in 10 men aged 60 years and over suffer from urinary incontinence, ¹² rising to 30% of those aged 85 years and over. ¹³ These figures probably underestimate the true prevalence, as most cases are believed to go unreported. In one European survey, only 26% of men with urinary incontinence sought medical help, ¹⁴ a problem that is likely to be associated with issues of masculinity and emotional inhibition. Thus, most men with urinary incontinence do not seek medical help and instead suffer in silence.

Voluntary control of bladder function is a precondition for a sense of normality that includes self-esteem, personal hygiene, and independent living. Urinary incontinence is thus not only a medical problem but also a psychosocial problem too. Left untreated, it can have a major impact on patient well-being. Common psychosocial problems include the risk of social stigmatisation, embarrassment, loss of self-esteem, and humiliation as well as increased risk of developing concomitant depression and anxiety.^{2,15} Urinary incontinence not only interrupts activities of daily living (ADL) but may also increase social isolation by stopping patients from going out for fear of smelling of urine or of experiencing involuntary leakage while in public.

Male urinary incontinence is a common health problem affecting millions of men worldwide most of whom do not seek professional help and appropriate treatment

1.4. Continence products for men

A range of continence products is available with the aim of helping men 'stay dry', so that they can live as close to a normal life as possible and enjoy a good quality of life free from the stigma of incontinence. Continence products broadly range from absorbent pads and adult diapers, to urinary sheaths (which are also known as penile sheaths or external condom catheters), to urinary catheters.

Absorbent products, some of which are designed for the male anatomy, are the most commonly used products and consist of pads for mild-to-moderate flow to adult diapers for moderate-to-heavy flow. Available in both disposable and reusable forms, they are designed to rapidly absorb urine and distribute it throughout the absorbent core, so drawing moisture away from the skin, and minimising adverse skin reactions and odour.

Despite the extensive variety of products available today and their widespread use, absorbent products have a number of significant drawbacks (Table 3), and have yet to meet major goals of incontinence care, which are to achieve freedom from leakage and preservation of skin health.



Table 3. Drawbacks associated with the use of absorbent incontinence products

- Perceived as feminine hygiene products
- Bulky in nature not always discreetly hidden under clothing
- Require frequent changes up to six pads per day
- High risk of leakage
- · Risk of urine stained clothing
- Odour of urine from leakage
- Chaffing and skin irritation
- · Disposal is difficult, especially for men of working-age and in certain working environments (e.g. building sites)
- Heavy environmental costs associated with disposal and/or repeated laundering of washable products

1.5. Urinary sheaths for male urinary incontinence

Absorbent incontinence products are usually perceived as feminine hygiene products, in contrast urinary sheaths have been exclusively developed for men and are of two main types: 16

- Two-piece urinary sheath in which adhesive is provided as a separate single- or double-sided adhesive strip or as an adhesive solution in a tube or bottle for application to the penis before fitting the sheath
- One-piece self-adhesive urinary sheaths in which the adhesive has already been applied to the inner surface of the sheath

The development of urinary sheaths has evolved considerably from the early two-piece sheaths, culminating in advanced products such as those

within the Conveen product range. One of the most modern urinary sheaths offers male incontinence patients a more discreet packaging solution. By diverting the urine to a urine collecting bag, urinary sheaths protect the skin from contact with urine and limit the risk of odour.⁶

With modern one-piece urinary sheaths and a range of urine bags, men now have a much wider range of incontinence products from which to choose and this should lead to better continence management and less disrupted lives. However, men are often not aware that there are alternatives to absorbent pads and diapers.

Proper management of incontinence can put an end to the fear of leakage in public and help male patients return to a normal life



Chapter 2

Choosing urinary collecting systems

Many men with incontinence still use absorbent pads as they are easy for healthcare professionals to prescribe and do not require training in their use. However, among urologists, urinary collecting systems are seen as an attractive alternative with theoretical advantages over absorbent products in terms of comfort, hygiene, clothing protection, and overall dryness.¹⁷ This has led to a change in the EAU guidelines on urinary incontinence, where collecting devices are now recommended for men with urinary incontinence without significant residual urine providing they can be applied easily and independently.⁵

2.1. Managing incontinence can impact quality of life

There is an abundance of evidence to suggest that compared with continent individuals of similar age and health, those with urinary incontinence experience a greatly diminished quality of life.² Among men, it can be the most disruptive, yet silent, assault on their masculinity. How incontinence is managed can, therefore, influence patient quality of life.

Data from a prospective, randomised, crossover trial in 61 adult male outpatients with stable, moderate-to-heavy urinary incontinence, in which study participants tested urinary sheaths for 2 weeks as well as their usual absorbent product for 2 weeks, showed choice of product had a profound impact on patient quality of life.⁴

Quality of life was measured with the King's Health Questionnaire (KHQ) and the Short-form 12 (SF-12) Acute Questionnaire following the use of urinary sheaths and the use of absorbent products. Results showed lower KHQ scores on all items, reflecting improvement in quality of life for urinary sheaths compared with the patient's usual absorbent products. Significant differences in favour of urinary sheaths were observed for 'limitations of daily activities' (-10.24 \pm 3.99, p=0.01) and 'impact of incontinence' (-7.05 \pm 3.45, p<0.05) (Figure 2).

On the basis of a 10-item patient preference questionnaire, a significant majority of patients preferred the urinary sheath to their usual absorbent product (Figure 3). Moreover, 91% of study participants said they would continue to use urinary sheaths. Compared with absorbent products, the urinary sheath was seen to offer patients significant improvements with respect to efficacy, self-image, odour management, discretion, and skin integrity.

Figure 3. Patient preference for urinary sheaths compared with usual absorbent products (AP)⁴

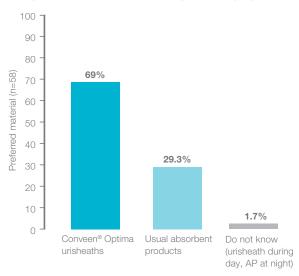
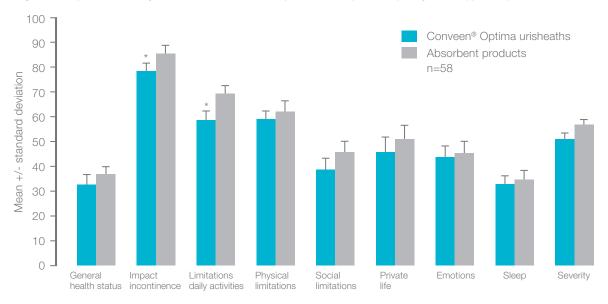


Figure 2. Impact of urinary sheaths and absorbent products on patient quality of life (*p<0.05)4



Urisheaths are an attractive alternative to absorbent products, and most specialists agree that their use enhances the physical and psychological well-being of incontinent men⁴

Preservation of skin health is one of the twin goals of incontinence care, as exposure to urine increases the risk of developing skin problems around the genitals and perineum. Although absorbent products may help keep bedding and clothing dry, these products tend to keep the urine in constant contact with the skin with potential to cause irritation, redness, peeling, and, in the worst cases, loss of skin integrity. This problem is most acute in nursing home patients where rates of incontinence are highest, 18 patients are often sedentary for long periods of time and absorbent pads may not be changed frequently to minimise costs.

For many men with urinary incontinence, urinary sheaths offer a more comfortable alternative to other incontinence products. Data from the prospective, randomised, crossover trial that compared urinary sheaths (Conveen Optima urisheath) with absorbent products showed them to be well tolerated by study participants. In this study, product safety was measured as the number of local adverse events. During the period when urinary sheaths were worn, there were four cases of skin irritation and one case of macuolpapular rash (leading to discontinuation).4 All cases of skin irritation resolved with improved hygiene. Keeping the skin clean, dry, and free from pressure are important measures that patients need to adopt in preserving skin health.¹⁹

Fitted correctly, a urinary sheath should not cause compression of the penis or become contaminated with urine and cause irritation or damage to the skin. Nonetheless, patients should always be monitored for skin health, tissue damage, and urinary tract infections (UTI), and the advice of a tissue viability nurse sought if any serious skin problems arise following application of a urinary sheath.¹⁹

Keeping the skin clean, dry, and free from pressure are important measures that patients need to take in preserving skin health when using urinary sheaths

2.2. Evidence-based guidelines support urinary collecting systems

Evidence-based guidelines in support of urinary collecting systems have followed publication of the first randomised controlled trial to compare the benefits of urinary sheaths with absorbent products on quality of life in men with moderate-to-severe incontinence.⁴

The guidelines, published by the EAU Working Panel on Urinary Incontinence in 2013, recommend urinary sheaths for men with urinary incontinence without significant residual urine.⁵



Chapter 3

Considerations when choosing collecting devices

Urinary collecting systems comprise two components – a sheath worn over the penis that is connected to a urine bag worn on the leg. Product performance under everyday conditions is the chief determinant of patient compliance with incontinence products. With urinary collecting systems this is governed not only by the design and ergonomics of the product but also by the type of material from which the product is made. Urine collecting bags are an integral component of a urinary collecting system and their design and ergonomics are as important as the urinary sheaths to which they are connected.

3.1. Choosing a urinary sheath

3.1.1. Benefits of a non-invasive procedure

Although long-term use of urinary sheaths may cause bacteriuria, they are not thought to increase the risk of UTIs when compared with other continence control measures.²⁰ Compared with indwelling catheters, urinary sheaths reduce the risks associated with an invasive procedure. They carry a much lower risk of bacterial colonisation and infection and, as such, are generally preferred for patients able to void spontaneously.²¹ A study of spinal cord injury patients showed that the use of urinary sheaths reduced the incidence of UTIs seven-fold compared with patients fitted with indwelling catheters,²² while another study showed urinary sheaths were not only less likely than indwelling catheters to lead to bacteriuria and symptomatic UTI but were also significantly less painful.23

3.1.2. Importance of correct assessment and fitting

Used properly, urinary sheaths can provide a secure and highly effective way to stay dry in a wide range of male patients with urinary incontinence (Table 4) but correct fitting of the sheath is key to successful adoption of a collecting system. By providing advice and thorough training, specialist continence nurses play an essential role in helping patients and their carers understand how good long-term results with urinary collecting devices can be achieved.

Table 4. Patients for whom urinary sheaths may be particularly suitable²⁴

- Patients with sphincter damage following prostatectomy
- Patients able to void without significant residual urine or in combination with intermittent catheterisation
- Patients with functional incontinence, such as those with poor mobility, dementia, impaired vision, or for whom getting to a toilet poses a safety issue
- Patients with poor skin integrity for whom a urinary sheath will allow drainage of urine away from the skin surface

The amount of assistance required to fit and change a urinary sheath will vary from patient to patient: for example, some will be independent and otherwise healthy and require no assistance following initial sizing, fitting, and follow-up,

whereas others will be in poor physical and mental health and require complete support. It is important to adapt the amount of assistance provided based on the ability of each patient. Patients should be encouraged to do as much of the process as possible for themselves, which is much easier with today's one-piece urinary sheaths.

Coloplast's Conveen Optima urisheath, for example, has been designed to ensure a comfortable and secure fit. It is available in different sizes and different lengths. Standard length is suitable for most men with a non-retracted penis. For other patients, especially those with a retracted penis, a shorter length is likely to be more suitable. This has less material in the sheath so it does not leave a roll of excess material at the base. A measuring guide makes it very easy to select the correct size of Conveen urisheath for a given patient and ensures there is no compression, discomfort, or leakage that may arise if the incorrect size is selected.

3.1.3. Quality of urinary sheath underpins success

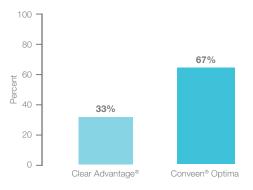
In its recommendation that urinary sheaths are appropriate for conservative management of urinary incontinence in men without significant residual urine, the EAU adds the important proviso that the sheaths should be easily and independently applied.⁵ Choice of sheath is, therefore, of prime importance in this context and, as clinical studies show, there is considerable variation in the performance of different products.^{6,7}

One early study that compared six self-adhesive sheaths showed a strong preference among users for the Clear Advantage® brand, especially with respect to secure fit; sheath detachment was identified as a problem with several products⁷ and has been known to discourage patients from continuing to use collecting devices. Subsequent to that study, a prospective, randomised, crossover study was carried out to compare the relative ease of use of Coloplast's urisheaths, comparing the high-performance Conveen Optima with Clear Advantage. The trial, carried out in 55 adult male outpatients with stable urinary incontinence, asked study participants to test the two Coloplast products. The objectives were firstly to measure patient preference for the two urinary sheaths and secondly to assess product performance with respect to ease of use, comfort, leakage, and preservation of skin health.6



Of the 36 participants who expressed a preference for product type at the end of the trial period, there was a preference for the high-performance urinary sheath in comparison with the older product; 60% of participants had been using Clear Advantage as their regular incontinence product prior to study entry and had been satisfied with this product (Figure 4).⁶

Figure 4. Patient preference for brand of urinary sheath⁶



67% (95% confidence interval 52% to 82%) preferred Conveen® Optima 33% (95% confidence interval 18% to 48%) preferred Clear Advantage®

These results suggest that differences in the design and quality of urinary sheaths can affect patient acceptability and preference for these products. For example, poorly fitting sheaths may cause problems⁷ and are likely to lead to low product acceptance among incontinent men. In contrast, Coloplast's high-performance urinary sheath (Conveen Optima urisheath) has been designed to offer men with urinary incontinence a product that provides a high level of comfort and security. This was reflected in study participants'

feedback on the two products in the comparative quality assessment trial, where, in comparison with Clear Advantage, the high-performance Conveen Optima urinary sheath was found to be:6

- Significantly easier to use both in terms of opening the pack and removing the sheath from the packaging
- Significantly less likely to develop wrinkles or bubbles when the sheath was being applied
- Significantly more secure immediately after application of the sheath
- Significantly more comfortable to wear
- Significantly more convenient in allowing drainage into the urine collecting bag during wear and much easier to connect and subsequently disconnect from the urine bag (for emptying)
- Significantly more discreet to carry around

Factors such as these are, therefore, important when selecting and securing a successful introduction to a urinary sheath.

In addition, about one-third of patients had their urinary sheath fitted by a continence nurse or carer, in which situation gloves were used. More than twice as many nurses/carers found it easier to fit the Conveen Optima urisheath than Clear Advantage.⁶

With Conveen Optima, men with urinary incontinence can gain the confidence to get back to doing what they love most in the company of friends and family

3.1.4. Latex and non-latex urinary sheaths

Traditionally, urinary sheaths were made of latex and this material continues to be used today. However, some men develop hypersensitivity to latex urinary sheaths that can lead to severe dermatitis and breakdown of the phallic skin.

Studies that have compared latex with silicone urinary sheaths suggest that those made from silicone are superior to traditional latex sheaths. Not only do they eliminate the risk of latex allergy but they have also been shown to bind more securely to human skin so reducing the risk of detachment and leakage.²⁵ Because they cause little compression to the penis, silicone urinary sheaths reduce the risk of penile ischaemia and damage to the skin. Moreover, clear silicone sheaths allow the condition of the patient's skin to be monitored without removing the sheath and have excellent oxygen and water vapour transmission properties so allowing the skin to breathe. 19 This is essential given that the penis is occluded for periods of up to 24 hours.

Consistent with the most advanced urinary sheaths available today, Coloplast's latest additions to its range of Conveen urisheaths are made from PSX silicone, a skin-friendly material that is also stretchy and breathable. Extra thought has been given to patients with humid or dry skin, for whom Conveen Prep® has been developed. This is a protective film that can be applied to the base of the penis before the Conveen urisheath is fitted. In addition, Coloplast's urisheaths are secured in place with balanced and skin-friendly hydrocolloid (GX) adhesive.

An effective urinary sheath is one that stays securely in place, is leak-free, comfortable to wear, easy to apply and remove, avoids skin damage, and channels the urine effectively into a urine collecting bag

3.2. Choosing a urine collecting bag

Studies show that urine bag design has a considerable influence on urinary sheath performance and illustrates how the quality of each component part of the collecting device can affect overall product performance.²⁶ Urine bags collect the urine voided via urinary sheaths or catheters and are connected to the sheath or catheter by an inlet tube fitted with a non-return valve. They also have taps for drainage. To minimise the risk of infection, the collection tubing and bag should always remain

below the level of the patient's bladder, while the drainage tubing should always be above the level of the collecting bag. For daytime use, men with incontinence can choose adjustable tubes to connect the urinary sheath to the urine collecting bag, which is then secured to either the patient's thigh or calf with leg straps. At night the bag is replaced with a larger night drainage bag that can be attached to the patient's bed (see Chapter 5).

Leg bag design has a considerable influence on urisheath performance

3.2.1. Sterile versus non-sterile collecting systems

UTIs are among the most common infections, especially in older people in whom incontinence is also most common. As noted earlier, conservative management of incontinence with urine collecting devices, especially urinary catheters, increases the frequency of bacteriuria and can predispose patients to risk of UTIs.²⁶

Absorbent products pose an increased risk of UTI too; a study carried out in nursing home residents showed the risk of developing UTIs was 41% among pad users compared with 11% for non-pad users (p=0.001).²⁷

Minimising the risk of bacterial infection is an important part of continence care and for which aseptic practice, including the selection of an appropriate collecting bag, needs to be considered.

3.2.1.1. Choice of collecting bag with urinary sheaths

Urinary sheaths, which are used externally, are by definition non-sterile and in most situations urisheaths can (and should) be used with non-sterile urine collecting bags (Table 5).

Several studies have shown that urinary urisheaths pose a significantly lower risk of bacteriuria and UTIs compared with invasive methods of bladder control.^{21,23}

3.2.1.2. Choice of collecting bag with urinary catheters

Urine collecting bags are also an integral part of bladder management by catheterisation, where issues of sterility are more important because of the greater risk of bacterial infection, especially with indwelling catheterisation.²³



For patients who require catheterisation, and especially prolonged catheterisation, intermittent catheterisation (including self-catheterisation) is considered the 'gold standard'.^{21,29} Sterile (aseptic) catheterisation, which includes the use of sterile urine collecting bags, has been advocated over non-sterile procedures in higher risk environments such as hospitals, because it reduces rates of bacteriuria and UTI.30 and in nursing homes because of the high risk of nosocomial infections.31 However, sterile catheterisation is not essential for all patients and for many (if not most) patients, especially those living in the community and performing self-catheterisation and where infection risks are much lower, clean intermittent catheterisation is a perfectly acceptable alternative.²⁰ In this situation, non-sterile urine collecting bags are appropriate (Table 5).

Table 5. Sterility considerations in the management of urinary incontinence

- Sterile urine collecting bags are recommended where risk of infection is high
 - Indwelling catheterisation in general
 - Intermittent catheterisation in nursing home patients
 - Intermittent catheterisation by carer or healthcare professional in the community
- Non-sterile urine collecting bags are recommended where risk of infection is low
 - In conjunction with urinary sheaths (e.g. Conveen Optima) in either hospital or the community
 - In conjunction with clean intermittent selfcatheterisation in the community

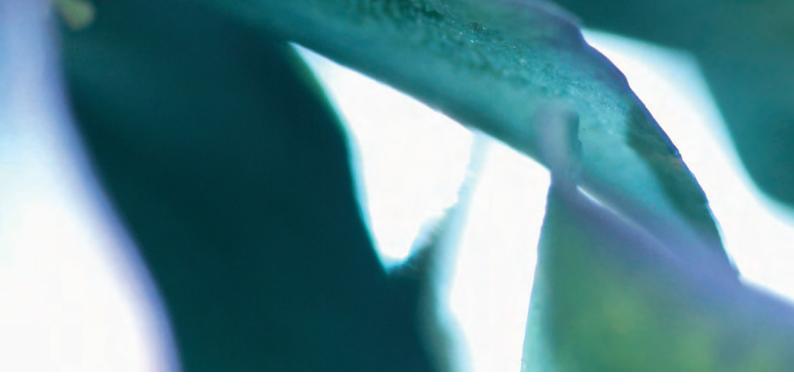
Coloplast manufactures a wide range of urine collecting bags that include both sterile and non-sterile bags, so that the collecting device can be customised to each patient's specific needs.

3.2.2. Anti-kink design for unobstructed flow

With any collecting device it is essential that the urine flows freely into the urine bag and is not obstructed. Coloplast's urine collecting bags have been designed to promote optimum drainage. The Conveen Security+® urine bag, for example, features anti-kink tubing that reduces the risk of backflow. The bedside drainage bag also features extra-long anti-kink tubing, which not only ensures free flow but also potentially reduces the risk of disconnection due to the extra length. Studies have shown that the prevalence of bacteria in the corrugated inlet tube with 'smooth' sections of the Conveen Security+ urine bag is equivalent to that observed in the inlet tube of the Conveen Standard urine bag.³² The bag, which is made from polyurethane, is soft and light and has a non-return valve to prevent backflow, thus making the bag more hygienic. Moreover, the exceptional flexibility of the non-polyvinyl chloride (PVC) tubing enables it to follow the natural movements of the leg, making the tubing just as discreet as the bag itself.

PVC-free products are not only beneficial to patients' health but as discussed in the next chapter have important environmental benefits too.

Conveen Security+ features anti-kink tubing that reduces the risk of backflow



Chapter 4

Environmental considerations – choosing the right materials

Coloplast is committed to minimising the negative impact on the environment from the production and use of its products through to their packaging and disposal. During product development, Coloplast assesses the environmental impact of all materials and processes used, as well as seeking ways to reduce any environmental impact.



PVC is a plastic material that is widely used in the manufacture of medical devices including collecting tubes, urinary catheters, and urine collecting bags. Phthalates are often used as a plastic softener in PVC materials and have recently been banned from use in children toys and cosmetics. At Coloplast, particular emphasis has been given to the use of non-PVC alternatives wherever possible, as this avoids the life-cycle hazards associated with PVC, notably the release of dioxins and hydrochloride acid following the combustion of PVC-related medical waste in incinerators.³³

No phthalates No PVC Sans phtalates Sans PVC

A selection of Conveen products is PVC- and phthalate-free, limiting their environmental impact and ensuring patient's health is not compromised. Boxes carrying the above sticker show the product is PVC- and phthalate-free

The Conveen Security+ urine bag, which is made from polyethylene and ethylene vinyl acetate and is therefore free of PVC and phthalates, epitomises Coloplast's approach to the development of incontinence products with low environmental impact. The Conveen Optima urisheath, made from silicone and worn for periods of up to 24 hours, is another example. Although the urisheath has to be disposed of in general household or hospital waste because of prior contact with body fluids, all associated packaging can be recycled. Being compact in size and requiring a once-daily change, it has lower environmental impact than disposable absorbent pads and diapers, which have to be changed up to six times a day. Even with washable absorbent products there are environmental costs associated with home or commercial laundering. Leakage associated with absorbent products leads to more frequent changing, wastage, and laundry, and exacerbates environmental impact.

Together, Conveen urisheaths and Conveen urine bags provide a reliable alternative to absorbent products that can be worn with confidence, a low environmental impact, and without compromising health



Chapter 5

Key features of the Conveen family of urinary collecting devices

Conveen is a range of sheath-and-bag bladder management solutions. It delivers reliable protection from the inconvenience and discomfort of urinary incontinence. The range is customisable so you can select a solution that suits your patient's needs, wherever he is on his journey to recovery.

Conveen® Optima

Conveen Optima is our high-performance sheath, designed to keep you dry all day.

Urisheath

- A Conveen Optima uses a balanced adhesive that's reliable and skin-friendly
- **B** Its anti-leakage features, such as the anti-kink bellow, guard against blockage
- C Its stretchy and breathable silicone ensures a perfect fit and easy, painless removal
- **D** It has a double-strip grip that enables easy, secure application
- E It comes in compact, discreet and convenient packaging













Conveen® Urine bags

Conveen urine bags are available in day and night versions – both ensure maximum protection from leakage.

Leg bag

- A Features anti-kink tubing that reduces the risk of backflow
- **B** The custom-designed clamp outlet is easy to operate, and it's also easy to verify it's closed properly
- C The soft backing makes it comfortable to wear
- D The chambered design reduces swaying when moving about
- **E** The discreet design and colour scheme reduces the bag's visibility under clothing

Bedside drainage bag

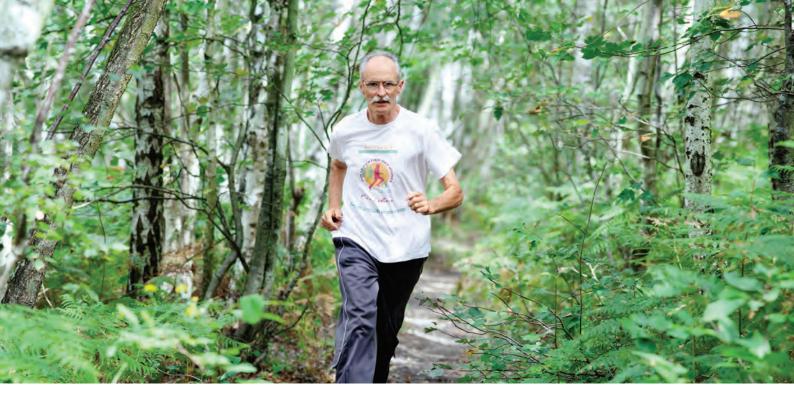
- **F** The bedside bag has a large capacity, making it easier for you to get a full night's sleep
- **G** It features an extra-long anti-kink tube that ensures free flow and reduces the risk of disconnection (providing freedom of movement in bed)

Conveen leg bag straps

Conveen leg bag straps keep your leg bag securely and discreetly attached to your leg. Neutral colouring ensures invisibility under clothing while the button-on/-off system makes it easy to remove the bag when emptying over the toilet.







Conveen® is a customisable solution, meaning you can find a reliable solution that meets your needs whatever your situation. Select a sheath and bag to customise your solution:

Level of incontinence	Sheath	Bag
4 6 0 0 0	Conveen Optima	Conveen Leg Bag 600ml
Occasional small dribbles or leakages		4
		Conveen leg bag
		800ml
Larger leakages or surges, a cup at a time		4
	Occasional small dribbles or leakages Larger leakages or	Conveen Optima Occasional small dribbles or leakages Larger leakages or



References

- 1. Leung FW & Schnelle JF. Urinary and fecal incontinence in nursing home residents. Gastroenterol Clin North Am 2008;7:697
- 2. Ko Y, et al. The impact of urinary incontinence on quality of life in the elderly. Am J Manag Care 2005:11:S103–111
- 3. Eastwood S, et al. Compromising and containing: self-management strategies used by men and women who live with multiple sclerosis and urinary incontinence. Aust J Holist Nurs 2002;9:33–43
- 4. Chartier-Kastler E, et al. Randomized, crossover study evaluating patient preference and the impact on quality of life of urisheaths vs. absorbent products in incontinent men. BJU Int 2011;108:241–247
- 5. Lucas MG, et al. Guidelines on Urinary Incontinence. European Association of Urology, 2013.
- 6. Pemberton P, et al. A comparative study of two types of urinary sheath. Nurs Times 2006;102:36-41
- 7. Fader M, et al. Sheaths for urinary incontinence: a randomized crossover trial. BJU 2001;88:367–372
- 8. Abrams P, et al. The standardization of terminology in lower urinary tract function: report from the standardization sub-committee of the International Continence Society. Urology 2003;61:37–41
- 9. Irwin DE, et al. Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study. Eur Urol 2006;50:1306–1314
- 10. Thomas P, et al. Reasons of informal caregivers for institutionalizing dementia patients previously living at home: the Pixel study. Int J Geriatr Psychiatry 2006;19:127–135
- 11. Campeau L. Male stress urinary incontinence: assessing patient-reported outcomes. Can Urol Assoc J 2011;5:273
- 12. Shamliyan TA, et al. Male urinary incontinence: prevalence, risk factors, and preventive interventions. Rev Urol 2009;11:145–165
- 13. Anger JT, et al. The prevalence of urinary incontinence among community dwelling men: results from the National Health and Nutrition Examination survey. J Urol 2006;176:2103–2108
- 14. Boyle P, et al. The prevalence of male urinary incontinence in four centres: the UREPIK study. BJU Int 2003;92:943–947
- 15. Wyman JF. Treatment of urinary incontinence in men & older women. Am J Nurs 2003;103(Suppl):26–35
- 16. Colley W. Products to help men manage incontinence. Nurs Times 2002;98:52
- 17. Chartier-Kastler E. How urinary sheaths benefit quality of life. Nurs Times 2011;107:20-22
- 18. Zimmaro BD, et al. Incontinence-associated skin damage in nursing home residents: a secondary analysis of a prospective, multicenter study. Ostomy Wound Manage 2006;52:46–55
- 19. Booth F & Lee L. A guide to selecting and using urinary sheaths. Nurs Times 2005;101:43
- 20. Wyndaele J-J. Conservative treatment of patients with neurogenic bladder. Eur Urol Suppl 2008;7:557–565
- 21. Ramakrishnan K & Mold JW. Urinary catheters: a review. Internet J Fam Pract 2005;3:doi: 10.5580/621
- 22. Esclarin de Ruz A, et al. Epidemiology and risk factors for urinary tract infection in patients with spinal cord injury. J Urol 2000;164:1285–1289
- 23. Saint S, et al. Condom versus indwelling urinary catheters: a randomized trial. J Am Geriatr Soc 2006;54:1055–1061
- 24. Brodie A. A guide to the management of one-piece urinary sheaths. Nurs Times 2006;102:49-51
- 25. Edlich RF, et al. Biomechanical performance of silicone and latex external condom catheters. J Long Term Eff Med Implants 2000;10:291–299
- 26. Watson A & Kuhn M. The influence of component parts on the performance of urinary sheath systems. J Adv Nurs 1990;15:417–422
- 27. Beveridge LA, et al. Optimal management of urinary tract infections in older people. Clin Interv Aging 2011;6:173–180
- 28. Omli R, et al. Pad per day usage, urinary incontinence and urinary tract infections in nursing home residents. Age Ageing 2010;39:549–554
- 29. Stöhrer M, et al. EAU Guidelines on Neurogenic Lower Urinary Tract Dysfunction. Eur Urol

- 2009;56:81-88
- 30. Prieto-Fingerhut T, et al. A study comparing sterile and nonsterile urethral catheterization in patients with spinal cord injury. Rehab Nurs 1997;22:299–302
- 31. Newman DK & Wilson MM. Review of intermittent catheterization and current best practice. Urol Nurs 2011;31:12–28
- 32. Coloplast Test Report. Bacteriological investigation of corrugated inlet tube: Conveen Security+ Urine Bag. Data on file, 1994
- 33. Wagner J & Green A. Correlation of chlorinated organic compound emissions from incineration with chlorinated organic input. Chemosphere 1993;26:2039–2054



Appendices

Fitting guide to Conveen urinary collecting devices

Like anything new, using a urisheath and urine bag for the first time or changing to a different type of collecting system can take a bit of getting used to. Patients can maximise security with the perfect fit by following these simple steps.

Using Conveen® urisheath and urine bag – fitting instructions

Although Conveen Optima is very reliable, it is important that you follow these fitting guidelines closely to make sure the urisheath works perfectly. Before fitting the urisheath make sure the penis is clean and dry. Trim pubic hair if necessary. Wash your hands.

Fitting the urisheath



Flip open the urisheath pack using your thumb nail to break the seal.



Remove the urisheath from the pack and place it over the head of the penis. Leave a small space between the end of the penis and the narrow urisheath outlet. Uncircumcised users should leave the foreskin in place over the head of the penis.

Removing the urisheath



Removal is easy and painless. Conveen Optima can be removed by detaching the sheath from the urine bag connector and carefully rolling it off the penis. If you need to, use warm soapy water to help remove the sheath. It can then be disposed of in a bin, with general household waste.



Pull the double strip to slowly unroll the urisheath all the way up the length of the penis. The urisheath should unroll smoothly and evenly.

Change the urisheath every day and change the bag according to recommendations from your healthcare professional. Both the collecting system and the packaging may be disposed of as normal household waste. Finish by washing your hands.



Gently sqeeze the urisheath around the shaft of the penis to ensure a secure fit.

To reduce the risk of skin irritation, allow the skin on the penis to breathe for short periods in between sheath changes.

Fitting the urine collection bag



Connect a urine collecting bag to the urisheath by inserting the bag connector into the urisheath outlet. Push together firmly for a secure connection.

Attach the bag to the calf or the thigh.

Empty the leg bag on a regular basis, when it is approximately two-thirds full.

Emptying the urine collection bag



It is advisable to select different collecting bags for day and night use. During the day, a smaller capacity bag can be worn for comfort and mobility. For nights, we recommend using a large capacity bag. This will minimise accidents and you avoid having to empty the bag during the night.



Calf worn bag



Thigh worn bag

Patient testimonials

Getting on with life is what everyone wants and that is why Coloplast has developed its Conveen Urinary Collecting System for male urinary incontinence. Here are testimonies from two patients that show how the Conveen Urinary Collecting System has transformed their lives.



"With Conveen, I am resuming activities I did before. Who knows, I might even get back to ballroom dancing".

Denis, Conveen user, France



"Now I don't even think twice about going out and about".

Bernard, Conveen user, UK

For Denis Fernadez, aged 65 years and recovering from prostate cancer surgery, Conveen has enabled him to resume an active life again and continue his passion for sport.

For Bernard Reilly, aged 51 years and also recovering from prostate cancer surgery, the Conveen Urinary Collecting System has enabled him to return to work and get his life back to normal.



The Coloplast story began back in 1954. Elise Sørensen is a nurse. Her sister Thora has just had an ostomy operation and is afraid to go out, fearing that her stoma might leak in public. Listening to her sister's problems, Elise creates the world's first adhesive ostomy bag. A bag that does not leak, giving Thora – and thousands of people like her – the chance to return to their normal life.

A simple solution with great significance.

Today, our business includes ostomy care, urology and continence care and wound and skin care. But our way of doing business still follows Elise's example: we listen, we learn and we respond with products and services that make life easier for people with intimate healthcare needs

Ostomy Care Urology & Continence Care Wound & Skin Care

