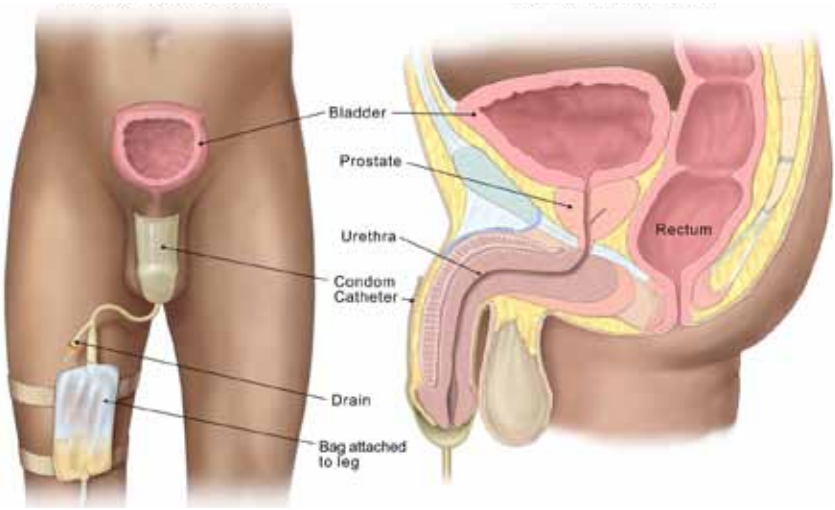
Evidence-based Guidelines for
Best Practice in Urological Health Care

Male external catheters in adults

Urinary catheter management

Condom Catheter
Urinary Sheath
Penile Sheath

2016



European Association of Urology Nurses

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Preface

The European Association of Urology Nurses (EAUN) was created in April 2000 to represent European urology nurses. The underlying goal of the EAUN is to foster the highest standards of urological nursing care throughout Europe. Improving current standards of urological nursing care is top of our agenda, with the aim of directly helping healthcare professionals in this field develop or update their expertise. To fulfil this essential goal, we have updated the EAUN guidelines published in 2008: The Male External Catheter.

With administrative, financial and advisory support from the European Association of Urology (EAU), the EAUN also encourages research and aspires to develop European standards for education and accreditation of urology nurses.

Local policies
We believe that excellent healthcare goes beyond geographical boundaries. This document is intended to support good clinical practice and should only be used in conjunction with local policies and protocols, and with recognition of the individual situation of the patient.

This text is made available to all individual EAUN members, both electronically and in print. The full text can be accessed and downloaded from the EAUN website (http://nurses.uroweb.org/) at no cost. Hard copies can be ordered through the web shop at the EAU website (http://uroweb.org), or by e-mail (eaun@uroweb.org).

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1. Introduction

Male urinary incontinence (UI) is common and may cause discomfort, embarrassment and disruption to everyday activities. For further information on the management of urinary incontinence, please refer to the EAU Guidelines on Urinary Incontinence at http://uroweb.org/guideline/urinary-incontinence/ and the 5th International Consultation on Incontinence at http://www.icud.info/PDFs/Incontinence.pdf. UI is defined as "*the complaint of any involuntary leakage of urine*". [1] The epidemiology of UI in men has not been investigated to the same extent as in women. The prevalence of UI ranges from 1 to 39%, depending on how UI is defined and which population has been included in the study. [2]
Clear risk factors have not been scientifically documented, but several medical correlates have been reported. Established risk factors predisposing men to UI include increasing age, presence of lower urinary tract symptoms, urinary tract infections (UTIs), functional and cognitive impairment, diabetes, neurological disorders, and prostatectomy. [2]

Containment products
Containment is important for people with UI when active treatment does not cure the problem, or when it is not available or possible. Some individuals may prefer to choose containment rather than undergo active treatment with its associated risks. This includes the use of absorbent pads, urinary catheters, external collection devices and urinal collection devices for men. A useful resource for healthcare professionals and patients can be found at: http://www.continenceproductadvisor.org/ [3]

Male external catheters
Some men who cannot benefit from active treatment of urinary incontinence may benefit from the use of a male external catheter (MEC). Recognising that few nurses have had education and training in the use of MECs, the EAUN decided to update the Male External Catheter guidelines.
MECs are well known in the field of urological, neurological and geriatric nursing, but knowledge about them varies greatly among regions, and it is the impression of the Working Group that more patients could benefit from their use if the assessment and instructions were correct and individualised for each patient.

Nurse education
The use of MECs is hardly taught to nurses, which paves the way for underuse and avoidable problems. To support safe, effective practice, it is vital that appropriate education and training are provided to ensure that practitioners have a clear understanding of urinary tract anatomy, assessment, correct procedures and the potential problems and complications that may be encountered.
In Europe, there is great variation in the level of education and practical training of nurses in urology, with the roles and responsibilities of nurses differing among countries. It is therefore difficult for any guidelines to fulfil all the requirements or expectations of individual practitioners. However, the EAUN Guidelines Group aims to ensure that every nurse and allied healthcare professional will gain some benefit from using these guidelines.

2. Methodology

2.1 Scope and purpose

The need for these guidelines
The MEC is a device with a definite role in the treatment of male UI, but is probably underused because of a lack of education. These guidelines are intended to fill the gap of (evidence-based) information and encourage healthcare professionals to consider this option more often.

Overall objective
These guidelines provide guidance to healthcare professionals, patients and their families for the correct assessment and standard use of MECs in men with UI. The aim is to expand knowledge regarding MEC products and provide practical help in using them.

The guidelines were developed to prevent unintended harm to patients and to enhance compliance with using MECs. We describe evidence-based or best practice for safe use of MECs based on the literature search and consensus decisions in the Working Group. The Group decided to include topics such as indications, contraindications and alternatives, nursing principles, and interventions in male external catheterisation, as well as patient education. They also included what was found on aspects that have influence on quality of life (QoL).

Expected benefits
The scope of these guidelines was established at the start of the writing process. Six PICO questions were posed to guide the literature review process (Chapter 14).

These guidelines, in which we include clear illustrations, detailed application procedures and extensive references, will help them to identify potential problem areas in the assessment, application and removal of MECs.

More specifically, these guidelines aim to support healthcare professionals in the prevention of complications of male external catheters, such as UTIs, irritative and allergic symptoms, compressive symptoms and pressure sores, skin lesions and leakage, and contribute to improving the QoL of MEC users.

Although these guidelines aim to be comprehensive, effective practice in assessing MECs and supporting patients who are going to use these devices can only be achieved if the nurse or practitioner has a clear and thorough knowledge of the urinary tract anatomy, the necessary understanding of basic nursing principles, and has been assessed in practice as competent in this procedure.

These guidelines are expected to have an impact on men with UI who could benefit from (partially) using MECs.

Limitations
The EAUN Guidelines Working Group has prepared these guidelines to help nurses assess evidence-based management and incorporate the recommendations into their clinical practice. These guidelines are not meant to be prescriptive, nor will adherence to them guarantee a successful outcome in all cases. Ultimately, decisions regarding care must be made on a case-by-case basis by healthcare professionals after consultation with their patients and colleagues, and using their clinical judgement, evidence-based knowledge, and expertise.

Composition of the team
The Working Group of these updated guidelines consists of nurse specialists Veronika Geng, Susanne Vahr and Hanny Cobussen-Boekhorst with support from Hanneke Lurvink from the EAUN Central Office and urologist Ian Pearce for the Indications chapter.

2.2 Literature search

The information offered in these guidelines was obtained through a systematic literature search and a review of current procedures undertaken in various member countries of the EAUN.

The initial search was done in December 2014 by Veronika Geng, Nurse Specialist, Germany.

Databases
- Pubmed
- Cinahl
- Cochrane

Search terms
- Male external catheters
- Condom catheters
- Urinary sheaths
- External urinary catheter

In July 2015 an additional search was performed by Susanne Vahr, Nurse Specialist, Denmark.

Databases
- Embase
- Cinahl
- Cochrane

Search terms
- Male external catheters
- Condom catheters
- Urinary sheaths
- External urinary catheter
- Complications

As a result of the lack of medical subject headings, (MeSH) the searches were performed with free text for male external catheter and condom catheter as well as urinary sheaths.

The search results were not limited to randomised controlled trials, controlled clinical trials, meta-analyses or systematic reviews. Additional searches were not limited to any level of evidence (LE). For the practical aspects of MEC application (see Appendices), brochures from manufacturers were used.

2.3 Limitations of the search

The search and data extraction were based on PICO questions formulated by the Working Group (Chapter 14).

Limitations of December 2014 search:
- English language
- Adults
- Human studies
- Age ≥ 19 years
- 2004-2014

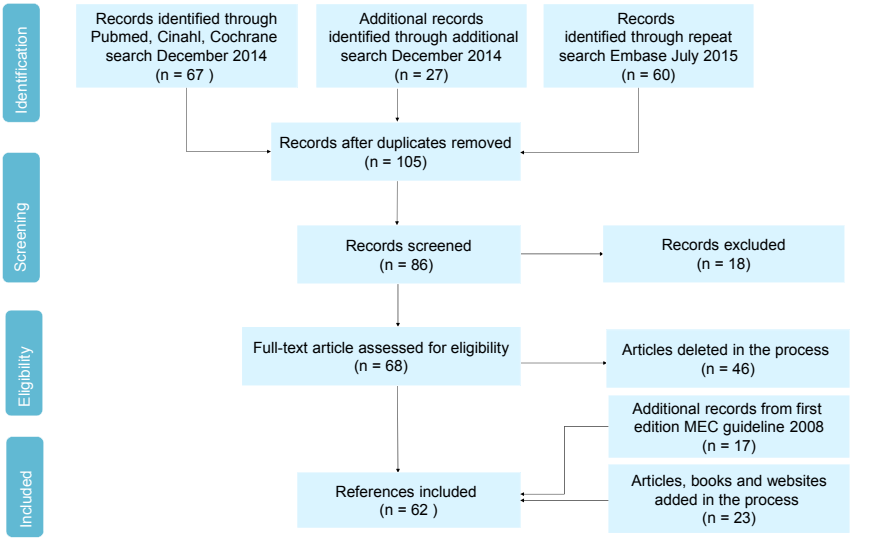
Exclusion criteria during abstract selection:
- Non-English-language studies
- Conference proceedings
- Paediatric studies
- Use of MECs for diagnostic reasons

It was a policy decision to restrict the search in the way described. After screening the records retrieved from the search of December 2014 (limited to 2004-2014), it was decided to do an additional search without limitation of year. However, it was decided not to use articles from before 2000 for the text on complications because those studies might have been performed with catheters made from material that is no longer used. After review, papers used in the original guidelines (2008) were included where text remained unchanged.
In the process of working with the articles, new references were found and added to the reference list, if they were relevant to the topic and cited in the text.

2.4 Search results

The searches resulted in:

Flowchart 1. Literature search "Catheterisation - male external catheters in adults"



2.5 Disclosures

Members of the EAUN Guidelines Working Group have provided disclosure statements of all relationships that might be a potential conflict of interest. This information is stored in the EAU database. The EAUN is a non-profit organisation and funding is limited to administrative assistance and travel and meeting expenses. No honoraria or other reimbursements are provided. This guidelines document was developed with the financial support of Coloplast, Hollister Incorporated and Manfred Sauer GmbH.

2.6 Limitations of document

The EAUN acknowledges and accepts the limitations of this document. It should be emphasised that the current guidelines provide information about treatment of individual patients according to a standardised approach. The information should be considered as providing recommendations without legal implications. The intended readership is practising nurses and other healthcare professionals. Cost-effectiveness considerations are best addressed locally and therefore fall outside the remit of these guidelines.

2.7 Review process

A blinded review was carried out by specialist nurses, urologists in various countries and a patient representatives. The Working Group revised the document based on the comments received and included relevant references received (also from after the search period). A final version was approved by the EAUN Board and the EAU Executive responsible for EAUN activities.

2.8 Rating system

The recommendations provided in this document are based on a rating system modified from that produced by the Oxford Centre for Evidence-based Medicine (OCEBM) in 2011. [4] External data extractors used the EAU data-extraction system for critical assessment of the papers identified.

Whenever possible, the Working Group graded treatment recommendations using a three-grade system (grade of recommendation; GR A-C) and inserted levels of evidence to help readers assess the validity of the statements made. The aim of this practice is to ensure a clear transparency between the underlying evidence and the recommendations given. This system is further described in Tables 1 and 2. Much of the evidence is weak, therefore, the Working Group decided to upgrade some of the recommendations. Upgraded recommendations are marked 'A*' meaning that the panel has agreed to recommend this even though the LE is 4.

Some of the literature was not easy to grade. However, if the Working Group thought that the information would be useful in practice, it was ranked as LE 4. Low-level evidence indicated that no higher level of evidence was found in the literature when writing the guidelines, but it cannot be regarded as an indication of the importance of the topic or recommendation for daily practice.

The Working Group aims to develop guidelines for evidence-based nursing, as defined by Behrens (2004): "Integration of the latest, highest level scientific research into the daily nursing practice, with regard to theoretical knowledge, nursing experience, the ideas of the patient and available resources". [5] The recommendations in these guidelines are based on synthesis of evidence from the articles. The Working Group based the text on the evidence of the articles whenever possible, but if evidence was missing, it was based on best practice and consensus.

Four components that influence nursing decisions can be distinguished: personal clinical experience of the nurse; existing resources; patient wishes and ideas; and results of nursing science. [5] This statement implies that, although literature is important, the experience of nurses and patients is also necessary for decision making. Consequently, it is not only the written guidelines that are relevant for nursing practice.

Table 1. Level of evidence (LE)

1a	Evidence obtained from meta-analysis of randomised trials
1b	Evidence obtained from at least one randomised trial
2a	Evidence obtained from one well-designed controlled study without randomisation
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
3	Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlations studies and case control studies
4	Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities and case reports

Adapted from Oxford Centre for Evidence-based Medicine (OCBM) [4]

Table 2. Grade of recommendation (GR)

Grade	Type of evidence - nature or recommendation
A	Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial
B	Base on well-conducted clinical studies, but without randomised clinical trials
C	Made despite the absence of directly applicable clinical studies of good quality

Adapted from Oxford Centre for Evidence-based Medicine (OCBM) [4]

3. Terminology

3.1 Male external catheter (MEC)

A MEC is used for treatment of urinary incontinence (UI) in men. This external catheter is not a true catheter, as it is not inserted into the urethra, body cavity, duct or vessel.

The MEC is a simple sheath that is placed over the penis, in the same way as a condom is used for contraception. Unlike a normal condom, a MEC has a drainage tube that allows urine to pass into a storage bag fastened around the leg. The MEC is a non-invasive device, as it makes no contact with the urethral mucosa. [6,7]

The MEC is also known as a: condom catheter, urisheath, condom drainage system, penile sheath, external catheter, urinary collection device, condom urinal, body worn urinal, and even a slang term, Texas Condom. [8] In these guidelines we consistently use the term male external catheter (or MEC) because it is the most commonly used name for this type of catheter.

3.2 Bacteriuria and urinary tract infection (UTI)

Bacteriuria
The method of urine collection has to be considered when defining bacteriuria. The aim is to determine what to advise in case of a (suspected) UTI. Today, we know that there is no fixed bacterial count that is indicative of significant bacteriuria that can be applied to all kinds of UTIs and in all circumstances. [9]

3.2.1 Asymptomatic bacteriuria

Asymptomatic bacteriuria is diagnosed if two cultures of the same bacterial strain, taken ≥ 24 h apart, show bacteriuria of ≥ 105 CFU/ml uropathogens. [9] Asymptomatic bacteriuria should not be treated with antibiotics.

3.2.2 Symptomatic bacteriuria

Symptomatic UTI is defined as a significant number of microorganisms in the urine that occurs together with symptoms such as dysuria, urgency, frequency, flank pain, costovertebral angle tenderness, suprapubic pain and fever. Further information can be found in the EAU Guidelines on Urological Infections: http://uroweb.org/guideline/urological-infections/

4. Indications, contraindications and alternatives to MEC

MECs may be used as a relatively non-invasive means of male urinary incontinence containment. MEC are designed not to treat UI, but rather to contain the symptom of urinary leakage regardless of the underlying aetiology and as such constitute an important tool in the armamentarium for UI management.
Whilst not truly invasive in the strictest sense of the terminology, MEC are not without their complications, both common and infrequent and as such should be considered on a practical level to be minimally or relatively non-invasive.

MECs are designed to function as an external urinary conduit facilitating the capture, containment and external drainage of urine from the external urethral meatus, via standard drainage tubing into an external catheter bag which may be either strapped to the thigh or lower leg whilst ambulant or attached to a free standing device employed most commonly overnight or if significantly immobile or bed bound.

Adequate function of a MEC relies on several interval factors, the most crucial being adherence of the device to the penile shaft skin. Without effective circumferential water tight adherence, urine will leak through the imperfect seal at points of weakness or loss of adherance may occur and the patient's symptom of UI will remain. It is vital, therefore to ensure that the MEC device is both sized and fitted properly to facilitate a good 360° seal. This seal must not only be water tight but needs to be secure for an acceptable period of time for each individual patient. Some patients require containment with a MEC overnight whilst others may require a more sustained level of control and the MEC needs to be capable of remaining with excellent adherence for as long as required without losing strength.

Given the length of time a MEC remains in situ, both for each individual MEC and, as an often long term containment strategy, the device needs to afford an element of comfort for the wearer in order to facilitate compliance and longevity of function. Uncomfortable devices often lead patients to manipulate and handle the MEC in an attempt to improve wearer acceptability with the resultant effect of reducing adherence, urine leakage and device malfunction.

Skin integrity may become compromised by a combination of excessive or uneven adherence, frequent device change, lack of comfort and difficulty with applying or removing the MEC and patients and careers alike should be counselled and warned to keep a watchful look out for loss of integrity which usually requires the temporary abandonment of MEC use to facilitate healing.

Ease of application and removal are thus essential to the long term acceptability of MEC, and may also influence the decision regarding the onset of utilisation for those patients with reduced dexterity.

In summary, an effective MEC is one that stays securely in place for an acceptable period of time, is leak-free, comfortable to wear, easy to apply and remove, avoids skin damage, and channels the urine effectively into a drainage bag. [10]

Specific patient groups
Several distinct patient cohorts are worthy of special mention with respect to MEC usage on account of their often unique collection of pre-existing influential issues.

Older people with UI form, perhaps, the largest specific cohort requiring special consideration for several reasons. Changes with natural ageing mean that all types of UI become more common with increasing age and this is commonly associated with a combination of reduced mobility, limited dexterity, social isolation and impaired cognition. Specific interventions, such as assisted toileting may be required to successfully institute MEC containment is this group. [3]

Younger patients may also struggle with MEC usage, often for different reasons relating to body image or perhaps changing body habitus in those patients still physically maturing and this group requires specialised and empathic MDT management often involving psychological support.

Patients with restricted or impaired dexterity will require greater input to enable independent MEC use and to prevent inherent complications from inadequately applied devices and this group in common with the very young may require more intensive training and support than others to successfully manage their MEC.

Combining various kinds of continence management
For some men isolated containment with MEC may not be either the best or indeed the most personally acceptable option for all daily life situations and different but complimentary methods may be employed. For example, intermittent catheterisation may be necessary if the patient cannot empty his bladder voluntarily, or a MEC may be used during the day or during certain circumstances or activities whilst absorbents may be preferred overnight, particularly for those patients who are restless and may inadvertently avulse the device leading to skin and penile trauma.

4.1 Indications

The mainstay indication for containment with MEC devices is UI and as a containment product MEC devices should be considered only if other curative treatment options have either failed or are deemed unsuitable, perhaps on account of a patient being unfit for any other intervention or are requested by the patient.

The usual scenarios are

1. Overactive bladder with urge urinary incontinence without a significant post void residual (PVR) urine in men.

2. Men with UI and a significant post void residual urine who are incapable or unwilling to undergo any other treatment or intermittently catheterise, and in whom there are no other complications of chronic urinary retention.
   Stress urinary continence as a consequence of external sphincter damage from prostatic surgery, (TURP, RRP) when further intervention e.g.: male sling or artificial urethral sphincter is either unsuitable of unacceptable to the patient. [11]

3. During periods of intense observation requiring strict fluid balance and an accurate knowledge of urine output when catheterisation is either unsuitable or impractical e.g.: extensive urethral stricture disease.

4. UI in men with neurological disorders and neuromuscular syndromes.[12]

5. UI in men with poor mobility, dementia, impaired cognition or impaired vision, or for whom accessing a toilet poses a safety issue.

For these latter indications, a social support or family network should be available to ensure that the MEC is used both appropriately and effectively with regular review to ensure its continued use is in the patient's best interests. [13]

MECs may also be used for diagnostic purposes. [14] This falls outside the scope of these guidelines.

4.2 Contraindications

Contraindications to MEC are few and can be divided into absolute and relative.

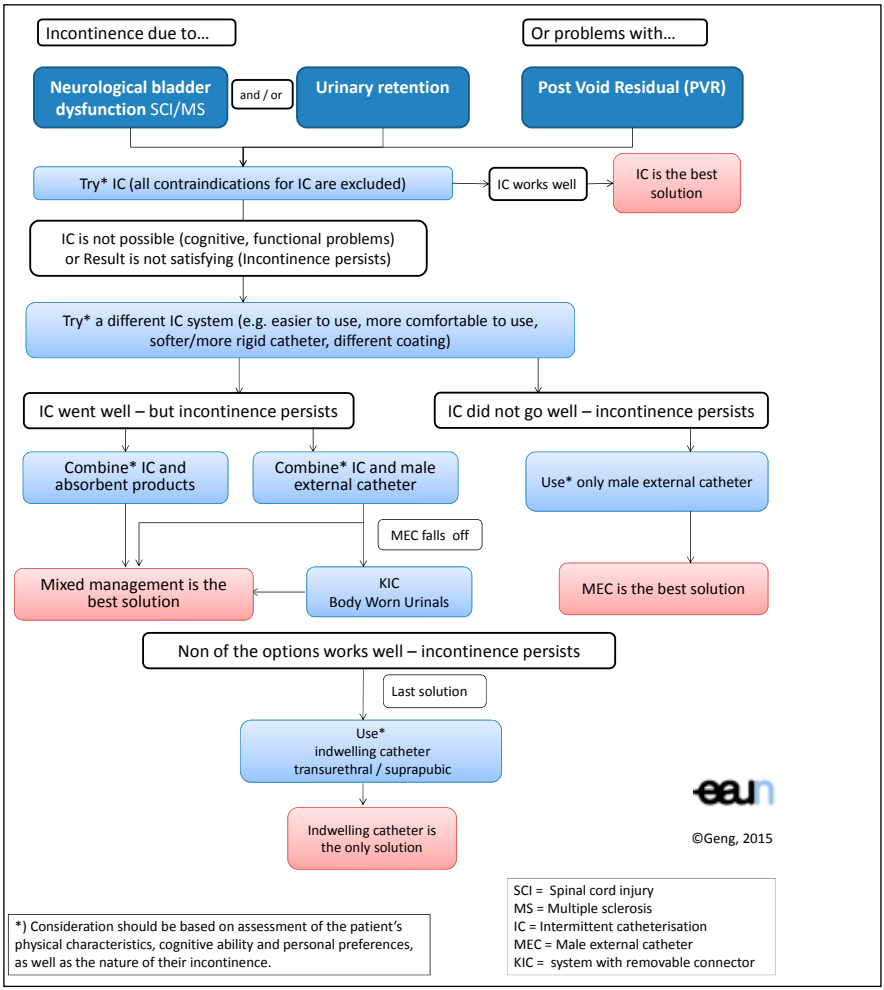
Absolute contraindications
The only absolute contraindication to the use of MEC devices is the known presence of high pressure chronic retention which may be the underlying causative pathology of UI. Whilst the use of MEC devices in such a scenario may contain the symptom of UI, it will not influence the high intravesical pressure and resultant impact on renal function and as such a more invasive definitive therapy should be employed. [15,16]
The use of conventional cystometry will delineate the intravesical pressure but simple renal tract ultrasound scan will demonstrate the hall mark feature of bilateral hydroureteronephrosis even before a decline in renal function is manifest.

Relative contraindications
Relative contraindications are more reflective of the fact that most clinical scenarios are better managed with alternative means e.g. low pressure chronic retention or bladder atonia are better managed with either long term catheterisation or intermittent catheterisation but if these are unsuitable or if the patient insists, the use MEC devices are viable since the intravesical pressure is low and thus the upper renal tract is safe. With MEC devices however, the bladder, in these circumstances will fail to drain and increase the risk of UTI, stones etc., thus whilst possible, this containment method is far from ideal.

Other limiting and relative contraindications for the use of MEC include dermatological issues such as excoriated penile skin, psoriasis and localised allergy to materials used as well as cognitive impairment, as such patient, may traumatically avulse the MEC resulting in loss of skin integrity. [10]

Body habitus may form a relative contraindications for some patients as a consequence of a physical inability to apply the device or perhaps visualise the penis thus hindering adequate application. In general patients with a high BMI are at greater risk of this as a combined consequence of blocked vision due to abdominal girth and a prominent supra public fat pad causing loss of visible and accessible penile length upon which to place the MEC.

Flowchart 2. Management of incontinence with PVR - decision tree



4.3 Alternatives to MEC

Alternatives to MEC vary and largely depend upon the underlying cause of the UI necessitating the use of MEC devices. Patients suffering from overactive bladder should be offered the full range of therapeutic options available including lifestyle modification, pharmacotherapy and surgery if fit whilst those for whom prostate enlargement and bladder outflow obstruction is a causative factor bladder outflow surgery should be considered and offered.
Alternatives aimed at resolving or containing the actual symptom of UI include the following:

- Intermittent catheterisation

For intermittent catheterisation, a catheter is passed into the bladder via the urethra, urine is drained, and the catheter removed. This procedure may be utilised with variable frequency in patients who fail to empty their bladders completely. In certain circumstances some men suffer UI only at high bladder volumes and but are unable to void naturally, under such circumstances, timely intermittent catheterisation may lead to resolution of UI. [11,17]

- Absorbent products/pads

Absorbent containment products may be single use disposable or reusable washable products. They differ in size, width, shape and design as well as the volume of urine that can be contained without pad leakage. The material and additional aspects such as super-absorber components also help to reduce leakage as well as improve patient acceptability. Skin irritation akin to adult nappy rash (ammoniacal dermatitis), leakage and odour are problems associated with all absorbent products. In many health care systems such containment products carry a huge financial burden for the patient who may either be expected to purchase their own pads or may only be offered the poorer quality pads free of charge.

- Clamp/penile compression device

Clamps have been available for several decades but there are no published studies that have evaluated their safety, comfort or effectiveness. Clamps are an effective option, but for short periods only, and provided cognitive ability, manual dexterity and bladder and genital sensation enable safe use. [18] The complications of penile clamps include oedema, urethral or penile erosion, urethral stricture disease and ischaemia, and their use must therefore be approached with great caution. [19] The penile clamp is absolutely contraindicated in case of detrusor overactivity or low bladder compliance because of the risk of developing high intravesical pressure, and in the presence of significant urinary reflux. [12]

- Male sling

The male sling provides a suitable alternative to MEC for the treatment of stress UI, usually secondary to prostatic surgery e.g.: TURP, RRP and is indicated in this group for the treatment of mild to moderate UI. Patients who are deemed fit enough should consider this in preference to MEC. Complications include urinary retention, infection and device erosion.

- Artificial urethral sphincter (AUS)

In common with the male sling, the artificial urinary sphincter is an excellent alternative to the use of MEC devices in medically fit patients suffering from stress UI. The AUS is suitable for moderate to severe incontinence and has excellent reported efficacy, durability and patient satisfaction. Complications include infection, erosion and mechanical failure.

- Indwelling catheter

Indwelling catheters made of latex or silicone material are placed in the bladder, via the urethral or suprapubic route and are held in place with an intravesical balloon. An indwelling catheter is an invasive device and is associated with significant complications such as UTIs and encrustation of the catheter. [19] The indwelling catheter may improve quality of life because it frees patients from toileting and wet containment products. Indwelling transurethral catheterisation and, to a lesser extent, suprapubic cystostomy are associated with a range of complications producing considerable health problems such as an enhanced risk for UTI. Therefore their use should be restricted. [12,19] For further information, please refer to the EAUN guidelines “Catheterisation - Indwelling catheters in adults. [20]

5. Complications

The complications related to the application of a MEC for urinary drainage, may be classified as irritative, allergic or compressive in aetiology. In a study of men with spinal cord injury [21] complications related to improper use of MECs were seen in 15% of patients. Most of the complications resulted from the use of rubber ducts with a penile sheath. Even though MEC products have developed a lot since 1981, complications are still reported (Table 3). The risk of complications is inevitably larger in patients with spinal cord injury because of decreased sensation.

5.1 Urinary tract infection

There are conflicting results when it comes to deciding if the risk of UTI is lower in men using MECs compared to indwelling catheters. [22-25] It is estimated that the incidence of UTI is 40% in men using MECs. [16,22,25] Saint (2006) found that the use of MECs is less likely to lead to bacteriuria, symptomatic UTI, or death than the use of indwelling catheters in men without dementia (LE 1b), however the study enrolled fewer patients than planned.
A comparison of bacteria in urine collected from MECs and indwelling catheters showed that the mean number of organisms per culture was significantly higher in MECs (LE3). [26] Urine from MECs had fewer biofilm-forming bacteria than urine from indwelling catheters. Much of the MEC-associated bacteriuria may represent contamination, resulting from a lack of protocols for collecting urine from MECs.

5.2 Irritative complications

Irritation is a non-allergic reaction. It is recognised as pink or red discolouration of the skin where the MEC or adhesive comes in contact with the skin. Irritation is also linked to fibroepithelial polyps. These are rare benign tumours of the glans penis of unknown pathogenesis. However, they have been linked with long-term use of MECs or prior penile surgery. A possible explanation is chronic irritation caused by urine leakage around an ill-fitting device, leading to maceration, ulceration, and subsequently causing the appearance of the polypoid masses. [27] Another explanation is that chronic venous congestion occurs secondary to extrinsic compression caused by the MEC, and leads to stromal proliferation. [28] Differential diagnosis includes condyloma acuminatum, giant condylomas (called Buschke-Löwenstein tumours), verrucous carcinoma, squamous cell carcinoma, urethral carcinoma and angiomyxoma.

5.3 Allergic complications

Allergic complications caused by latex are well known. This cell-mediated hypersensitivity may develop toward an allergen to which the patient has been exposed for many years. Immediate hypersensitivity is usually a response to a naturally occurring protein in rubber latex and occurs 5-30 min. after the patient is exposed to a latex MEC. The reaction is more pronounced than irritation and produces erythema, and the skin appears more reddened or

inflamed. The skin may also take on a smooth stretched appearance. The reaction subsides quickly when the MEC is removed. [29]

The development of material used for MECs has reduced the risk of allergic reactions but because they are a long-term complication, attention should be paid to choice of MEC material. Condom-related allergic contact dermatitis can occur up to 48 h after the initial application of the MEC, and it frequently presents with oedema and dermatitis of the penile glans and shaft or the scrotum. In severe cases of prolonged contact, epidermal sloughing of the entire penile shaft may occur. [30,31]

Although uncommon, it is important to be aware that oedema of the penis can cause problems with bladder drainage as a result of pressure on the urethra.

Epicutaneous patch testing is regarded as the best method for diagnosing allergic contact dermatitis.

Fig. 1. Erythematous and oedematous eruption on the penis

(Source: N. Milanesi (IT)/John Wiley & Sons)

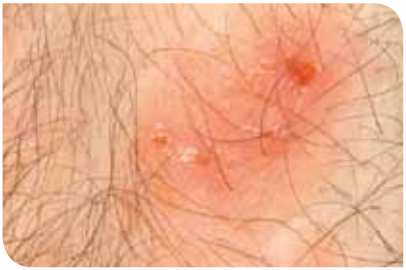


Fig. 2. Allergic contact urticaria caused by latex

(Source: Healthline.com)

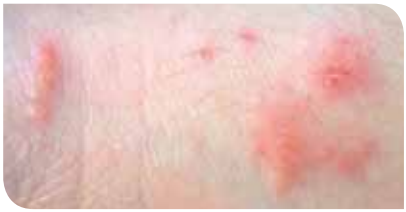


Fig. 3. Contact dermatitis

(Source: Healthline.com)

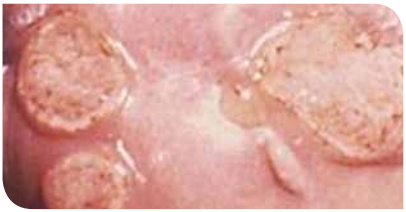


Fig. 4. Granuloma inguinale

(Source: Healthline.com)

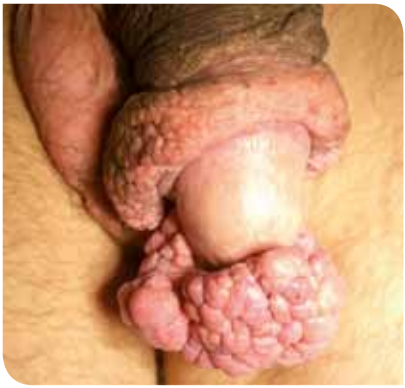


Fig. 5. Fibroepithal polyp
(Source: H. Yan (CA))

5.4 Compressive complications

The lack of pressure and/or pain sensation in most patients with spinal cord injury results in an increased risk of compressive complications. Compression by MECs may cause penetrating or non-penetrating lesions. If the patient is not assessed properly and the size of the MEC is wrong, strangulation of the penis may occur. There are reports of patients who have developed discolouration and subsequent gangrenous changes of the penis because of compression from MECs. [32-35] Gangrene is a type of necrosis caused by a critically insufficient blood supply and is seen rarely in patients using a MEC.

Fig. 6. Gangrene due to insufficient blood supply
(Source: H Özkan (TR)/John Wiley & Sons)

Table 3. Complications from studies (2000-2015)

UTI	44% (LE 1b) [25,26]
Irritative complications	Case reports [27,36-41]
Allergic complications	Case report [31]
Compressive complications	Case reports [32-35]

Recommendations	LE	GR
Describe protocols for proper use of MECs	4	C
Observe/inspect the penile skin carefully when changing the MEC	4	A*
Ask/check the patient for latex and other allergies	4	A*
Refer the patient to patch testing if oedema or dermatitis of the penile glans or shaft is observed [30,31]	4	C

An A grade recommendation is a strong recommendation despite level 4 evidence.*

6. Products and materials

There are a variety of products available for the management of UI, and it is important that healthcare professionals have a comprehensive knowledge of both products and application techniques before applying a MEC. [7,13]

6.1 Common MEC types

[7,42]

a. **Self-adhesive MEC (one-piece system)**
Self-adhesive MECs consist of three parts: the connecting tube, buffer zone and adhesive zone. The size of the three parts differs between companies and products.

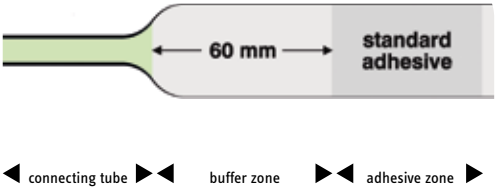


Fig. 7. The 3 parts of a self-adhesive MEC
(Source: Manfred Sauer GmbH)

Fig. 8. Various self-adhesive MECs
(Source: unknown)

b. **MEC with separate fixation (two-piece system)**
   a. MEC with double-sided adhesive
   b. MEC with skin glue (tube/spray)
   c. MEC with Velcro or external bandage

6.2 Special MEC types

a. **MEC with balloon principle**
The inflatable retention ring secures the catheter and can be easily deflated for removal. The retention ring must be positioned behind the head of the penis.

Fig. 9. MEC with balloon principle
Cook® Nonadhesive Silicone Condom Catheter
(Source: Cook Medical)

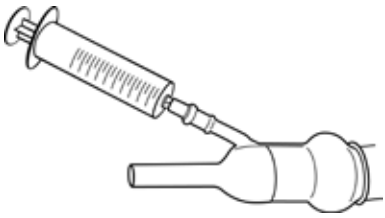


Fig. 10. Inflating the ring of a MEC with balloon principle
(Source: Cook Medical)

b. **Drip urinal.** This consists of a tubular sleeve, which encompasses the penis at one end and a hose-fitting outlet at the other end. The outlet can be drained by means of a tap. Some drip urinals allow for connection of multiple drainage bags in order to decrease reservoir emptying. [43]

Fig. 11. Drip urinals with different taps
(Source: Manfred Sauer GmbH)

c. **Pubic-pressure** MEC/body-worn urinals. These are designed for men who find traditional MECs unsuitable, or if the MEC is not successful; for example, retracted penis or if there are irritants in the urine (e.g., following chemotherapy). The MEC is held close to the body by waist and groin straps. This pressure allows the penis to protrude into the MEC. This system is not suitable for overnight use because of urine leakage.

d. **Male external device**

This device is placed on the glans of the penis and can be used by men with a retracted penis.

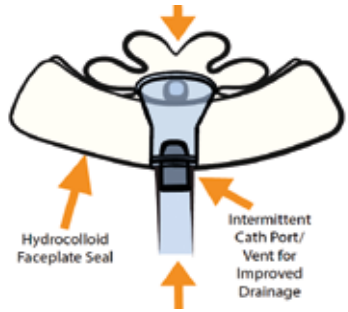


Fig. 12 & 13 MEC that is applied to the glans of the penis

Men's Liberty™

(Source: BioDerm)

e. **KIC Sheath, Connector and KIC Sheath Expander**

Fig. 14a KIC Sheath Expander

KIC-System®

(Source: Manfred Sauer GmbH)

Fig. 14b KIC Sheaths

Fig. 14c KIC Connectors with and without connecting tube

A special MEC with a hole and a connector instead of a fixed tube to catheterise more than once a day. With the MEC Expander the opening of the male external catheter can be widened and pulled up to allow disinfecting and catheterisation. After catheterisation the MEC is pulled down again and reconnected to the drainage bag. The MEC can be fixed in position with doubled-sided adhesive tape or liquid skin adhesives.

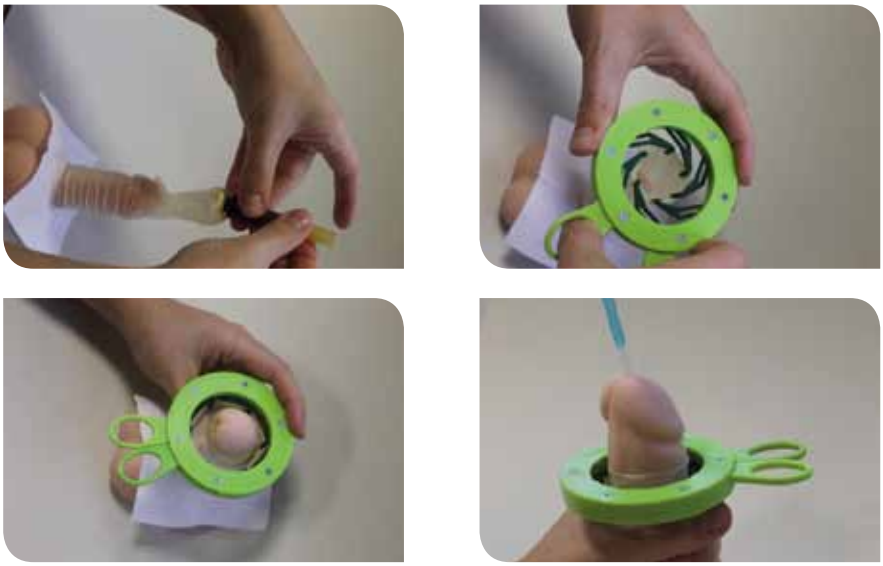


Fig. 15. Step 1, 2, 3 & 4 of the use of the KIC Sheath Expander KIC-System®
(Source: V. Geng/ Manfred Sauer GmbH)

6.3 MECs with special features

a. **MEC that contains an anti-reflux valve** (inner flap)
Prevents urine backflow and leakage.

Fig. 16. Latex MEC with an anti-reflux valve
Extended Wear Male External Catheter
(Source: Hollister Incorporated)

b. **MEC with applicator or special help stripe**
These types of MEC improve handling. The loop of the help stripe can be pulled which makes rolling out the MEC easier.

Fig. 17. MEC with help stripes
Conveen® Optima urisheath
(Source: Coloplast)

Fig. 18. MEC with adapter
Urimed® Vision Ultra Short
(Source: BBraun)

c. **MEC with anti-kinking/twisting features**
Some MECs have features intended to improve drainage by reducing kinking and twisting at the distal end, near the connection to the drainage bag tube. [10]

Fig. 19. MEC with double convolutions that resist kinking and twisting
Everyday Wear Male External Catheter
(Source: Hollister Incorporated)

d. **MEC with anti-blow off features**
Some MECs have features intended to reduce the likelihood of the sheath blowing off at high urine flow rates. [10]

6.4 Adhesives for MEC

There are different types of adhesives that are used to attach MECs to the penis.

a. **Self-adhesive MEC**
The ready-to-use condom has a sticky film on its inner surface, which attaches the MEC to the penis. The MEC can be rolled up and fixed in place. There are variations among the different types of adhesives, the position where the adhesive is positioned on the MEC, as well as how large the adhesive area is.

b. **Adhesive strips (tape/liners)**

Some MECs require a double-sided adhesive strip to attach them to the penis. The adhesive strips are placed onto the penis (encircling it) and the MEC is rolled over the penis, attaching to the adhesive strips. The thickness and size of the strips can vary.

Fig. 20. Adhesive strips
(Source: V. Geng/Manfred Sauer GmbH)

Fig. 21 a, b, c. Double sided adhesives
(Source: Manfred Sauer GmbH)

c. **Skin adhesives (spray and paste)**
There are non-self-adhesive MECs that do not contain an adhesive film, so they require application of a skin glue onto the skin before rolling the MEC over the penis.

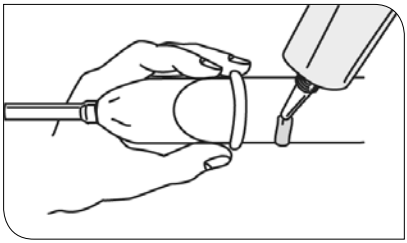


Fig. 22. Application of glue
(Source: Manfred Sauer GmbH)

d. **External fixatives (elastic foam or latex with Velcro)**

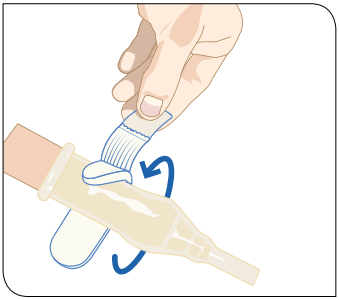


Fig. 23. Velcro fastener for fixation of the MEC
Ruecco Fix
(Source: Teleflex Medical)

Reusable foam and elastic strips, secured by Velcro, are available. Securing a MEC to the penis without using any adhesives generally results in less secure fixation. However, some men prefer this method; especially in cases where the catheter is removed and replaced frequently. [44] Using external fixatives may be associated with an increased risk of penile strangulation. External fixatives are sometimes placed on the end of the MEC for extra security (also when using a one-piece system).

e. **Skin adhesive strengthener**
Skin adhesive strengthener has a high content of alcohol that gives it cleaning, degreasing and disinfecting properties. It forms an elastic film on the skin, which allows the skin to breathe. Cleansing of the skin and formation of the film generally improve the adhesive strength of a MEC (self-adhesive, with skin adhesive or adhesive strip). In addition to these properties, skin adhesive strengthener can protect the skin.

6.5 Materials used for MECs

a. **Silicone**
Silicone is a translucent and breathable material that is biocompatible. Allergic reactions are rare. Its “skin-friendliness” can be considered its greatest advantage. In addition, the translucent material provides a view of the skin that allows one to recognise any irritation or emerging skin problem.

b. **Polyvinyl chloride**
Polyvinyl chloride (PVC) is a synthetic and resistant material, which may be exposed to sunlight, urine and mechanical impact. The production of PVC, however, requires the incorporation of plasticisers. Such softeners may be hazardous in long-term users, which should be taken into consideration when deciding to use PVC products for a long period.

c. **Polyurethane**
Polyurethane (PU) is a synthetic material and many latex-free MECs are made from PU. PU MECs are thinner than other types. This results in improved wearer comfort compared to other materials. Some types of PU may cause allergic skin reactions. However, these PU types are not usually used in MECs.

d. **Latex**

Latex is a soft and flexible natural product. Unfortunately, some patients may have latex sensitivities and develop an allergic reaction. For this reason, in several European countries (e.g., the UK, the Netherlands and Sweden) the use of latex products in the medical environment is slowly being phased out. There are several alternative (latex-free) products available. In patients with adhesive problems, latex MECs could be helpful because their elasticity is not matched by alternative MECs.

6.6 Urinary bags and collecting systems

The choice of drainage bag is dictated by several factors:

- reason for use
- intended duration
- patient mobility
- patient choice.

Consideration should be given to the following.

Bag capacity and placement

The size of leg bags ranges from 200 to 900 ml but usually a 500-ml leg bag is used. Patients might use a smaller bag (200-250 ml) for sports, or in summer time (e.g., when wearing shorts) or a larger one (1.5-2 l) (e.g., at night).

Fig. 24. Leg bag
Conveen® Active leg bag
(Source: Coloplast)

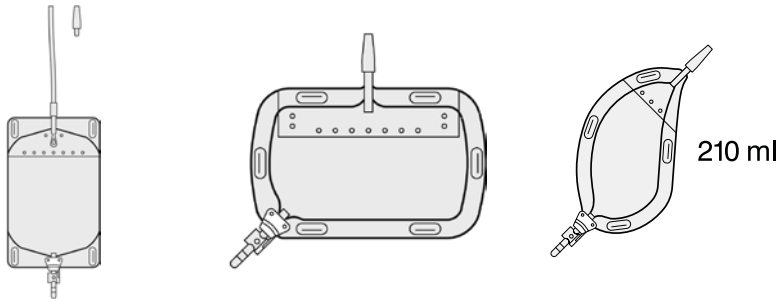


Fig. 25, 26, 27. Leg bags in various sizes
(Source: Manfred Sauer GmbH)

Fixation

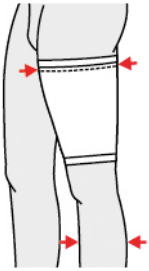


Fig. 28 & 29. Various leg bag holders

(Source: Manfred Sauer GmbH)

Sometimes an external waist belt is used for fixation of the urinary drainage system (leg bag holder) to ensure, that no strain is placed on the MEC.

Fig. 30. Waist belt for fixation of the urinary drainage system

(Source: Manfred Sauer GmbH)

Tubes and taps

There are at least three different tube lengths: direct connection (without tube), 10 cm and 30 cm. Some manufacturers may offer additional lengths. Some tubes can be made to the correct length by the patients themselves. Selection of the correct length of tube is necessary to prevent any twists that might result from coiled tubing.

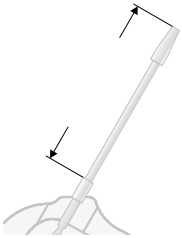


Fig. 31. Tube length

(Source: Manfred Sauer GmbH)

Choosing a tube to connect the urinary bag to the MEC is dependent on the radius of the tubes of the MEC and the urinary bag. Several connecting tubes (adapters) are pictured below.

Different kinds of taps are pictured below.

Figs. 32. Tube without adapter, 33. Tube with universal adapter, 34. Tube with rigid universal adapter
(Source: Manfred Sauer GmbH)

Fig. 35., 36. & 37. Valve taps to close a catheter: swing tap, turn tap or slide tap
(Source: Manfred Sauer GmbH)

Recommendation	LE	GR
In case of urine leakage or retracted penis consider a MEC with special features (see Chapter 6.3)	4	C

7. Principles of management of nursing intervention

MEC offer the advantage of diverting the urine to a bag, thus decreasing urine odour and protecting the skin from contact with urine. MEC may reduce the risk of complications associated with navigating the barrier protecting the urinary tract from stool. This may be especially true in the presence of liquid stool. [22,45]

7.1 Assessment including measuring

Before you start the assessment, the patient should be informed about the procedure and you must obtain informed consent from the patient.

For elderly persons, expectations of assessment and treatment may need to be modified to fit in with specific circumstances, needs, and preferences, while taking into account any loss of capacity for consent. When the healthcare professional is dealing with a frail elderly patient with urinary incontinence, collaboration with other healthcare professionals such as elderly care physicians is recommended. [3]

Assessment involves considering the patient's individual situation, measuring and selecting the proper devices:

1. Patient situation
   a. Is there an indication for MEC (chapter 4)
   b. Are there any contraindications (chapter 4)
   c. Are there more suitable alternatives (chapter 4)
   d. Continence symptoms and history of management
   e. Is the patient's clinical condition suitable
   f. Physical examination
   f. i. Penile skin condition (see chapter 7)
      ii. Retracted penis (see chapter 7)
   g. Mental acuity: Is the patient able to handle the MEC (cognitive, psychological) or if not, is a relative or healthcare professional able to assist
   h. Dexterity and Mobility - is the patient able to handle the MEC in case of impaired mobility or problems with hand/finger movement
   i. Home environment [46,47]
   j. Is the product available for the patient [7]
   k. Is there any preference for a product by the patient
   l. Is the cost acceptable

2. Measuring
   a. Size and length
   b. Using measuring tools

3. Selecting
   a. Choice of material
   b. Choice of application technique
   c. Choice of urinary drainage bag

7.1.1 Patient situation

Each patient should be individually assessed, as there is no single product that will meet all patients' needs. Patients must have sufficient penile length and girth, and they or their carer must be competent and willing to use the device.

The objective for fitting a MEC is to maximize the user's quality of life. [48] Bath et al (1999) [29] stated that some nurses find the process of assessment and fitting a MEC difficult due to their embarrassment regarding the intimate nature of the procedure.

A full assessment involves the collection of data and information relating to each individual's incontinence problems. [48] The assessment should ensure that the MEC is the most appropriate management choice and will not result in problems that deserve more active intervention.

Patients with cognitive impairment may try to remove their MEC, which will cause pain and possible tissue injury. Therefore, these patients should be carefully assessed before they are given these products. [8]

There is a definite need for compliance when using a MEC. Therefore, both patient and carer need to discuss the issue before a decision is finally made to use this device. [8]

7.1.2 Measuring

In order to find the appropriate size of the MEC, the circumference of the penis needs to be measured. The penis should be measured at the shaft where its diameter is largest in order to assess the correct size. [46] During measurement, the patient should be seated on the edge of a bed or chair with their legs slightly spread. In this free position both the scrotum and penis are in their natural anatomic orientation and can best be measured. The actual MEC size of the penis may be hard to determine if it ranges between two sizes. Should this situation occur, the patient should try both sizes at home. MEC materials are sufficiently flexible and allow a snug, but not tight fit. Many manufacturers and suppliers of MEC offer sizing guides (for example cardboard moulds or patterns), to help determine the size that will ensure safe and comfortable wear. [8,44] It is important to note that manufacturer sizes may vary, and sizing guides provided by one manufacturer should not be used for another.

Listed below are various size ranges provided by four manufacturers:

- Sauer Continence 18, 20, 22, 24, 26, 28, 30, 32, 35, 37, 40 mm
- Coloplast 21, 25, 28, 30, 35, 40 mm
- Hollister Incorporated 25, 29, 32, 36, 41 mm
- B. BRAUN 25, 29, 32, 36, 41 mm

Fig. 38. MECs in various lengths
InView Silicone Male External Catheter
(Source: Hollister Incorporated)

It is more important to determine the exact diameter of the penis to fit the correct size of the MEC than the length of the penis. All MECs currently available will fit most penis lengths, except when the penis is very small or retracted.
Nevertheless some manufactures have different lengths so the optimal size and length can be chosen.

Fig. 39. Measuring device
(Source: Manfred Sauer GmbH)

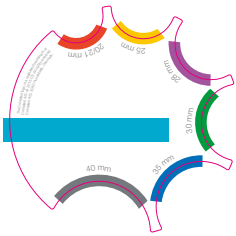


Fig. 40. Measuring device
Conveen® measuring guide
(Source: Coloplast)

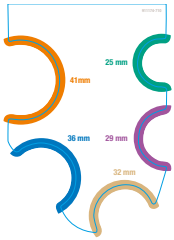


Fig. 41. Measuring device
InView Global Sizing Guide
(Source: Hollister Incorporated)

Retracted penis
Penile retraction occurs when the penis retreats inside the prepubic fat. This is a common occurrence in older men. If there is some penile retraction, the patient may be able to use a shorter length MEC. If total penile retraction is observed when the patient is sitting down, neither a standard nor short length MEC will stay in place and may fall off. [49]

Assessing penile retraction
Have the patient stand (if possible) and observe penile length. Gently press back on either side of the penis towards the pubic area to expose as much retracted length of the penis as possible. Observe the change in length and position. If the seated penis length is less than 5 cm, use a shorter length MEC. [7,49]

Special MECs are available on the market for patients with a shorter or retracted penis. Since a retracted MEC is shorter in length than a regular MEC, there is less area for the adhesive side of the catheter. Therefore, it is most important that the correct male external catheter size is selected. To apply the MEC, the patient should lie on his side. In this position, it is easier to reach most of the penis to attach the MEC. When the MEC is placed in the correct way, it can "handle" a retraction of the penis better. [7,49]

In the case of retracted penis there are some special MECs (e.g., BioDerm) or MECs with a shorter area of glue, or stronger glue. To apply the MEC, it is helpful if the patient brings the

penis to an erection. The patient can do this at home if possible. Therefore, a vacuum pump could be helpful.

7.1.3 Selecting

One- or two-piece MEC

The selection of a one- or two-piece MEC is a matter of personal preference, but for reliability and ease of use, most patients prefer to use a one-piece system. However, a two-piece MEC can be beneficial for those whose glans is larger than the shaft of the penis or where the patient has developed sensitivity to the adhesives used in the one-piece systems. Select a sheath that is easy to apply, as ease of application promotes confidence in users.

External fixation enables the MEC to be removed and intermittent catheterisation to be performed, but does not offer the security of internal fixation.

Drainage bag

The choice of drainage bag is dictated by several factors:

- Reason for use
- Intended duration
- Patient mobility and activities
- Patient preference

Consideration should be given to the bag capacity and placement. Either leg or bed bags can be used.

There are different sizes of bags. A patient might use a smaller bag during the day and a larger one at night.

The leg bag, body worn bag or waist suspended bag need to be attached properly, in order to allow urine to flow into the bag without difficulty.

Fig. 42. Leg bag

Comfort Leg Bag

(Source: Manfred Sauer GmbH)

Fig. 43. Leg bag

Bendi Bag

(Source: Manfred Sauer GmbH)

The leg bag can be placed at different positions on the leg: thigh, knee (special bag needed), and under the knee. A leg bag is the best choice for ambulatory patients. The bag is most commonly fastened around the thigh or with two straps. Sleeves and belts hold the bag safely and may be more comfortable. As the urine bag fills it becomes heavier and may stretch the straps. The urine bag should not be allowed to fill to the point of discomfort, but should be emptied when 2/3 full.
When the urine bag fills it becomes heavier and may stretch the straps. The urine bag should not be allowed to fill to the point of discomfort, and should be emptied when two-thirds full.

It is recommended to change the urine bag at least once weekly, but in many hospitals, the bag is changed every time that the MEC is changed. Changing the urinary bag depends on local or national policies or standards.

Fig. 44. Example of a leg bag for a wheelchair user
Comfort Leg Bag
(Source: Manfred Sauer GmbH)

- Adjust seating for wheelchair users, if necessary, to allow better drainage.

A bed bag/night drainage bag can be used instead of a leg bag and needs to be placed below the person to permit the flow of urine. It is important to choose the drainage bag that best meets the needs of the patient. [50]

- Ensure the urine bag is of the correct size and that it is well supported to avoid dragging on the sheath.

In case of impairment of hand function or vision, the type of tap can be an important factor for patients to be as independent as possible when emptying the bag.

Testing sensitivity

- Test the product for sensitivity, bearing in mind that some patients are allergic to latex.

For a flowchart on how to select the best urinary bag for the patient please refer to:
Appendix D: Flowchart MEC - Urinary bag decision tree

7.2 Application of the MEC

Step by step procedure: see Appendix A

7.2.1 Patient preparation

It is not advisable to shave the pubic area as this can cause skin irritation, but hair can be trimmed if necessary, to prevent it being caught in the sheath. [7]
Alternatively a hole can be torn in a tissue then placed over the penis to push the hair back. Some MEC include a hair guard.

7.2.2 Applying adhesives

See Appendix A

7.2.3 Skin care and meatal cleansing

The skin should be dry and undamaged before placing the MEC onto the penis. If the skin is undamaged, normal personal hygiene is sufficient.

Skin care products
When using silicone MEC, skin care products should not be used because they will reduce the adhesiveness of the MEC (Coloplast product information). In the case of skin care problems when using non-silicone products, there are different skin care products available on the market to help keep the skin healthy. A moisturizing cream should be pH neutral, oil free, and unscented. It should be free of soap and other cosmetic ingredients. [7]

Avoidable skin care products
An oil-based moisturising cream may change the integrity of the glue and affect the adhesive leading to leakage or displacement of the MEC. Perfume, soap or other cosmetic ingredients can irritate the skin, causing fungal skin infections, skin damage or abrasions and allergies.

When skin care problems are solved, the patient can return to normal personal hygiene in most cases. The skin also has a self-healing function.

7.3 Observation of the applied MEC

Frequent monitoring of the device is needed for effective use of this product. [16]

An hour after first application and with every catheter change, the MEC should be carefully observed to see if it fits well, tubes are not kinked, and there is no leakage and no pain.

7.3.1 Skin irritation

The skin should be carefully examined for signs of soreness or irritation. This is particularly important for patients with neurological deficits, who may be unaware that the sheath is too tight or causing skin problems. [29]

Nurses must inform caregivers and patients who may not be accustomed to this type of product that skin irritation may occur. They should be advised to remove the MEC immediately

if skin irritation occurs and gently wash and thoroughly dry the area to remove any residual adhesive. [29] The area should be dried and may be left open to the air unless blisters have formed and have exuded fluid. A clean non-occlusive dressing may be placed over the affected area. [29] This type of MEC should not be applied again and the incident should be reported to the clinician. The reaction should be recorded in the patient's records. [29]

In people with reduced or no skin sensation due to spinal cord injury or multiple sclerosis, an ill-fitting MEC could cause a pressure sore or skin lesion. Therefore, in these patients, it is necessary to observe the skin once daily.

7.3.2 Leakage

If a MEC does not remain secure for a 24 hr period the likelihood is that:

- stronger adhesive is needed
- the MEC is too large
- incompatibility of products,
- incorrect application technique
- penile retraction is present
- UTI
- mobility or activity of the patient
- aggressive urinary output (occurs in cases of UTI and chemotherapy)
- sweating
- pubic hairs
- combination of the problems mentioned above

Leakage prevention

In the event of a large volume urine loss a MEC containing an anti-reflux membrane can be useful in maintaining the integrity of the adhesive and protecting against leakage.

For details on how to manage the various problems, please refer to appendix C Troubleshooting.

7.3.3 Kinking

Avoid kinking or twisting of the sheath or the drainage bag as this allows urine to pool, thereby weakening the adhesive or blocking drainage completely. [7]

7.3.4 Changing interval

Daily changes of sheaths are recommended for all users when daily hygiene is performed. When the MEC falls off or leakage occurs it should be changed more often and if this recurs the patient should be reassessed.

It is recommended that the urine bag should be changed at least once a week. In hospitals, the bag is changed every time the MEC is changed due to the risk of cross contamination. Changing the urinary bag should follow local or national policies or standards.

7.4 Removing the MEC

Remove the MEC and the tape simply by rolling them off. Usually, the adhesive comes off with the MEC when removed. However, if there is adhesive remaining it can be washed with skin care products or rubbed off. Do not remove the adhesive with solvents, such as acetone or similar substances, since this will disrupt the natural oil balance of the skin and may cause chapping and cracking, leading to inflammation. Non-solvent based adhesive remover pads are available, but water and soap are recommended. In special cases, products used in stoma care could be used. [8,43,44]

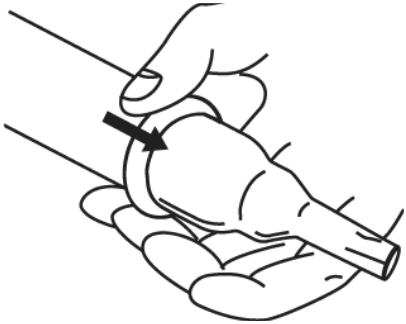


Fig. 45. MEC roll off
(Source: Manfred Sauer GmbH)

7.5 Collecting a urine sample from a MEC

Patients with symptoms such as dysuria, urgency, frequency, flank pain, costovertebral angle tenderness, suprapubic pain and fever may have a UTI and a urine sample should be sent for culture. Urine samples should be collected using a protocol that minimises contamination from the genital mucosa and perineal skin. [51] Guidelines recommend the collection of a mid-stream specimen in adults. The study by Nicolle (1988) [52] and Ouslander (1987) [53] found no difference between bacteriuria in urine collected from a clean MEC compared to urine from a sterile in-and-out (intermittent) catheter.

How to collect a urine sample

1. Meatal cleansing with water and soap
2. Dry the skin carefully
3. Put on a new MEC and attach a new urine bag
4. Collect the urine sample from the sampling port from the first voided urine [25,52]
5. Take the urine to the laboratory immediately or refrigerate the urine sample immediately after collection to prevent false results

Recommendations	LE	GR
Patients with cognitive impairment should be carefully assessed to determine if they are able to fit and manage a MEC [8]	4	C
Measure the length and the circumference of the penis at its widest point to fit the MEC in the correct way	4	A*
Assess the correct length of the inlet tube, taking into account whether the patient is a wheelchair user, a walker or bedridden	4	A*
Assess hand function of the patient and valve taps before choosing a urinary bag for the MEC	4	C
Shorten pubic hair to prevent it being caught in the sheath	4	C
Skin should be observed before fitting a MEC		
Skin should be observed after MEC is applied	4	C
Avoid creams and powders as they affect the adhesion of the MEC [54]	4	C
Hydrocolloid could help healing if skin is damaged	4	C
Skin should be observed after removing the MEC	4	C
Change the MEC daily [23,55]	4	B
Use a non-sterile urinary bag	4	C
Secure the urinary bag to allow free urine flow	4	C
Empty the urinary bag when two-thirds full	4	C
Change the urinary bag at least once weekly or follow local policy.	4	C
Follow protocols for collecting urine samples for urine culture from a MEC [51-53]	2a	B
Collect the first voided urine within an hour after MEC change from the sampling port in the drainage tubing [51-53]	2a	B

An A grade recommendation is a strong recommendation despite level 4 evidence.*

8. Nurse education

Several articles have shown that nurses have not been trained in how to use MEC and do not educate patients in using MEC. [18,46,47]
Training in proper use and frequent monitoring of the device is needed for effective use of MEC. [16]

Table 4. Nurse education for male external catheterisation

Maintain knowledge/skill in:	Rationale
Various types of MEC	To ensure the patient gets the best product for the individual situation
Indications for MEC	To ensure the patient meets requirements for treatment To ensure the treatment is beneficial for the patient
Anatomy and physiology of the urinary tract	To understand the impact of external catheters on the urinary tract To comply with requirements for catheterisation
Assessment of the patient before applying a MEC	To help the patient understand the benefits of treatment
Education and counselling of the patient	To help ensure concordance and compliance
Proper use and monitoring of the MEC	To ensure safe and effective use of MEC and reduce the risk of complications

9. Patient education

A study by Macaulay (2015) showed that only one patient out of 34 had been instructed in how to use a MEC. [18]

This checklist is intended to assist healthcare professionals to check whether all the information that patients/relatives need to know about MEC has been provided.

Table 5. Checklist for patient education

Patients need to know

- Why MEC is necessary and is the best choice
- Basic anatomical knowledge about the urogenital tract
- How to check the expiry date of the material before use
- How to prepare the MEC for use
- How to perform the MEC procedure
    - name, size and material of the MEC
- Which difficulties may occur during or after the MEC is applied
- Observational aspects during application of a MEC
    - how to observe the penile skin
    - urine drainage tube is not kinked
- Changing intervals for the MEC
- How to avoid UTI
- How to recognise symptoms or the common signs of UTI
    - burning on urination
    - frequency and/or urgency
    - pain
    - offensive smelling urine
    - cloudy/dark urine
    - feeling tired or shaky
    - fever or chills
    - haematuria [56-58]
- How and when to remove the MEC
- Availability of appropriate urinary drainage
- When to contact the healthcare professional, in case of:
    - pain
    - skin problems
    - problems applying the MEC
    - MEC falls off
    - incontinence episodes or leakage
    - symptoms of UTI

10. Patient Quality of Life (QoL)

The MEC can give men who suffer from incontinence greater confidence, comfort and QoL.

Urinary incontinence can have a significant detrimental effect on a person's body image and self-esteem as it undermines society's norms relating to body control. This can be further complicated by the use of devices to control urinary incontinence. Drainage systems are discreet and reliable systems that can have both physical and psychological benefits.
A full continence assessment is paramount for a successful outcome as there are several potential problems associated with this method of management. [48]

Body Image
Loss of control over bladder function whether through accident, disease or age can have a detrimental effect on a person's perception of himself and his self-esteem. This in turn can have an impact on his social and family interaction.
[18,59]

11. Documentation

When a patient starts to use a MEC, the following data must be collected and documented:
- Indication for using MEC
- Residual volume
- MEC type, length and size
- Problems negotiated during the procedure. [29]

A diary could help to monitor problems with the MEC as well as incontinence problems. The duration of keeping a diary depends on the individual patient patient's problems. For an example of a diary, see Appendix E Voiding diary

Documentation has to follow local policy.

Recommendations	LE	GR
Offer patients an individualised care plan based on the above criteria, bearing in mind the patient's and caregiver's lifestyle and the impact this will have on the patient's quality of life [60]	4	C
Complete diary to monitor problems and assess incontinence episodes [9]	2	B

12. Abbreviations

AUS	artificial urethral sphincter
CEBM	Centre for Evidence Based Medicine
GR	grade of recommendation
IC	intermittent catheterisation
IDC	indwelling catheterisation
KIC	removable adapter system of Manfred Sauer
LE	level of evidence
MDT	multidisciplinary team
MEC	male external catheter
MS	Multiple sclerosis
MeSH	medical subject headings
PICO	patient problem or population (P), intervention (I), comparison (C) and outcome(s) (O), the four parts of an answerable clinical question
PVR	post void residual
QoL	quality of life
RRP	retropubic radical prostatectomy
SCI	spinal cord injury
TURP	transurethral resection of the prostate
UI	urinary incontinence
UTI	urinary tract infection

13. Figure reference list

14. PICO questions

According to the Centre for Evidence Based Medicine (CEBM), "one of the fundamental skills required for practising EBM is the asking of well-built clinical questions. To benefit patients and clinicians, such questions need to be both directly relevant to patients' problems and phrased in ways that direct your search to relevant and precise answers."

A well-built clinical foreground question should have 4 components. The PICO model is a helpful tool that assists in organising and focusing the foreground question into a searchable query. Divided into the PICO elements helps identify search terms/concepts to use in your search of the literature.

- P = Patient, Problem, Population (How would you describe a group of patients similar to you? What are the most important characteristics of the patient?)
- I = Intervention, Prognostic Factor, Exposure (What main intervention are you considering? What do you want to do with this patient? What is the main alternative being considered?)
- C = Comparison (Can be None or placebo.) (What is the main alternative to compare with the intervention? Are you trying to decide between two drugs, a drug and no medication or placebo, or two diagnostic tests?)
- O = Outcome (What are you trying to accomplish, measure, improve or affect? Outcomes may be disease-oriented or patient-oriented.) [61]

PICO for "Catheterisation - male external catheters in adults" guidelines

Topic	
Population *Condition, disease severity and stage, comorbidities & patient demographics*	Men with urinary incontinence
Intervention *Dosage, frequency and method of administration*	Use of a male external catheter
Comparator *Placebo, usual care or active control*	Use of pads or naps or being incontinent or use of an indwelling catheter or use of an intermittent catheter
Outcome *Health outcomes: morbidity, mortality, quality of life.*	Urinary symptoms / quality of life / incontinence, urinary complications such as UTI, allergic reactions

PICO 1

Are there any advantages or disadvantages compared to other continence devices in treating incontinence with male external catheters?

PICO 2

Are there factors in product quality / material aspects that predict a better outcome in

- *handling the products*
- *complications*
- *incontinence accidents*
- *skin condition*

PICO 3

Is there any evidence that nurse education influences the results or prevents complications in males with MEC

PICO 4

Which issues have to be considered before fitting MEC to get the best results in continence and prevent complications?

PICO 5

Is there any evidence on using MEC related to the prevention of pressure sores, skin lesions/ allergies or leakage

PICO 6

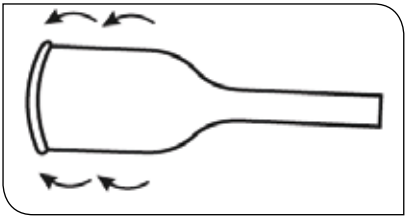
Is there any evidence on MEC compared to other catheters or on special nursing interventions to prevent urinary tract infections

15. Appendices

Appendix A. MEC application by a healthcare professional

A1. Preparations

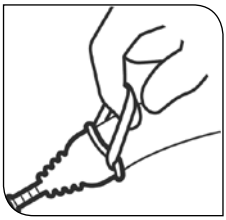
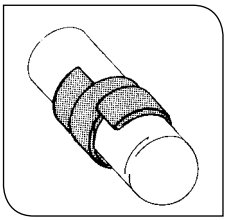
Intervention	Rationale
Wash your hands before (and after) the application and use gloves.	To prevent cross contamination.
Gather the equipment: • MEC • drainage bag (leg or bed) with tubing • water, soap, wash cloth, towel • scissors if needed	To ensure that the application process proceeds without any disturbance.
Explain the procedure to the patient.	To gain consent and co-operation and to ensure the patient understands the procedure.
Read the manufacturer's instructions before applying a MEC with special features.	To ensure patient safety.
Wash the penis with soap and water	To ensure adhesion of the MEC.
Do not use re-hydrating soap as it may cause the adhesive to fail. If that is the only cleanser available do not put on a new MEC directly.	
Rinse and dry.	
Wait 5 to 10 minutes Wait for at least 15-20 minutes after a bath or shower before application.	
Inspect the penis to make sure it does not have any broken or reddened skin.	To determine if a MEC can safely be used.
Trim the hair on the penis and its base.	The hair will not stick when the adhesive is applied.
Protective cloth placed over the base of the penis.	Can also assist in preventing hair from getting caught in the adhesive.
Another tip to keep the hair out of the way and to get a clean dry field around the base of the penis is to tear a small hole in the centre of a paper towel and then slip this over the penis to the base. [44]	

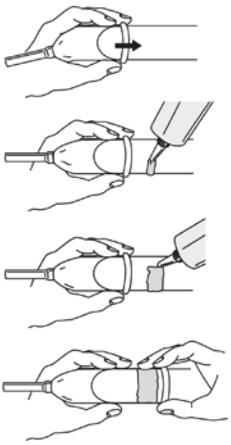
Roll out the MEC as specified by the manufacturer's instructions before rolling over the penis. [62]	 *Fig. 46. Roll out the MEC* *(Source: Manfred Sauer GmbH)*
If the patient is not circumcised, hold on to the foreskin when you put on the MEC.	Pulls forward the retracted penis and makes it easier to apply the MEC Keeps the foreskin in the right place.
Leave 2-3 cm space between the tip of the penis and the end of the MEC.	More than 2-3 cm might promote catheter twisting and restrict the urine flow.
It is preferable if the penis is erect, but it is not absolutely necessary. If no erection is present, stretch the penis slightly by pulling.	It is easier to put the MEC over the penis.

A2. Procedure for applying MEC with adhesives

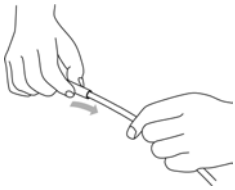
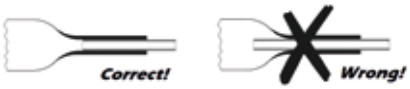
Intervention	**Rationale**
Check patient's records for allergies. If there is a possibility that the patient may be allergic to the MEC material or adhesive, do a skin test on a small area of skin before applying.	To prevent an allergic reaction in the patient.

Self-adhesive MEC	
Stretch the penis gently as you roll on the MEC. When the MEC is unrolled, press it against the penis so that it adheres. No other glue or adhesive strip is needed.	 *Fig. 47.a, b, c. Press the MEC against the penis* *(Source: Manfred Sauer GmbH)*

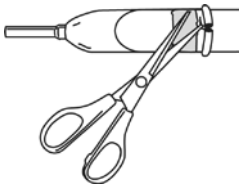
	Fig. 48. Self-adhesive MEC with a help stripe to roll on the MEC *(Source: Coloplast)* 
MEC with tape strip	
The tape strip is adhesive on both sides. A band of adhesive 2-3 cm wide is preferred.	To achieve the best adhesion of the MEC.
Apply the adhesive double-sided tape in a spiral overlapping fashion around the base of the penis.	*Fig. 49. Spiral overlapping of the tape stripe* *(Source: Manfred Sauer GmbH)* 
Do not stretch the strip.	Make sure it is not too tight.
Roll on the MEC over the tape and press to attach. In the case of hydro-colloid tape, it is recommended that pressure is applied with the hands for about 30 seconds.	To achieve the best adhesion of the MEC. The warmth of the fingers will increase the adhesive strength. *Fig. 50 Apply pressure on the MEC* *(Source: Manfred Sauer GmbH)* 

MEC with liquid adhesive	
Apply the adhesive, in small quantities, in a ring on the middle of the penis shaft. Do not put adhesive on any skin defects.	To ensure the adhesion process is successful.
Spread the adhesive well and uniformly.	
Unroll the MEC over the adhesive.	To achieve adhesion of the MEC to the skin.
Do not wait too long before applying the MEC.	Or the glue may dry.
Press tightly on the MEC.	 *Fig. 51. Application in 4 steps* *(Source: Manfred Sauer GmbH)*

A3. Procedure for connecting the drainage bag

Connect the drainage bag with tube to the connector tip.	To allow continent urine drainage into the urinary bag.
Make sure the system is free of twists and kinks.	
When attaching a leg bag, adjust the length of the inlet tube, before connecting the MEC to the leg bag.	 *Fig. 52. Adjusting the length of the inlet tube* *(Source: Manfred Sauer GmbH)*  *Fig. 53a. & b. Correct and wrong way to connect the MEC and the connector tube* *(Source: Manfred Sauer GmbH)*

A4. Final check

Pay special attention to the foreskin of an uncircumcised male and make sure the foreskin is returned to its natural position.	Failure to return the foreskin can lead to swelling and possible constriction.
Check for proper size and adhesion of the MEC.	To prevent any complications in case of misfitting.
If necessary, to avoid pressure marks or if the penis retracts during micturition (emptying the bladder), the remaining rubber ring behind the adhering area can be removed by cutting or tearing the rim while the MEC remains adhered. [8,43]	Be careful that the skin is not damaged (special scissors are available). *Fig. 54. Cut the rim* *(Source: Manfred Sauer GmbH)* 

Appendix B. Patient's teaching procedure for applying MEC

B1. Preparation

Intervention	Rationale
Gather the following items: o Waterproof pad or bath towel o Bowl of warm water, soap, washcloth, and hand towel o Correct size of MEC (small, medium, large, extra large) o Velcro, tape, or other type of sheath holding material o Urine bag with tube	

B2. Procedure

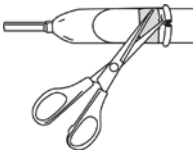
• Wash your hands and your penis with soap and water. Rinse and dry your penis carefully.	To avoid cross contamination.
• Inspect your penis.	To ensure that it does not have any broken or reddened skin.
• Gently roll the MEC over your penis. Leave 2-5 cm of the MEC at the end of your penis.	To create enough space between the penis and tube.
• Wrap the sheath holder around the MEC at the base of your penis. Do not wrap the sheath holder too tightly because this may stop blood from going to your penis.	To prevent hair from becoming caught in the adhesive.
• Connect the MEC to the tube of the urine bag.	To ensure continent urine drainage.
• If you are using a small leg bag, use the catheter leg strap that came with your kit to secure the urine bag to your leg just below your knee. Leave some slack in the tube so the catheter will not be pulled when you move your leg.	To prevent disconnection of the tube from the drainage bag.
• The urine collection bag must be placed so that your urine flows downward. If you are in bed, you may attach the collection bag to your bed under the mattress. If you are sitting in a chair, you may attach the urine bag to the chair below the cushion you sit on.	

Source: Virtual labs media library http://virtuallabs.stanford.edu/

Appendix C. Troubleshooting

Monitor and note any difficulties that may occur when using MEC. If there are any problems, act according to local policy/protocol. Identification and management of problems are essential when caring for patients with MEC and their caregivers.

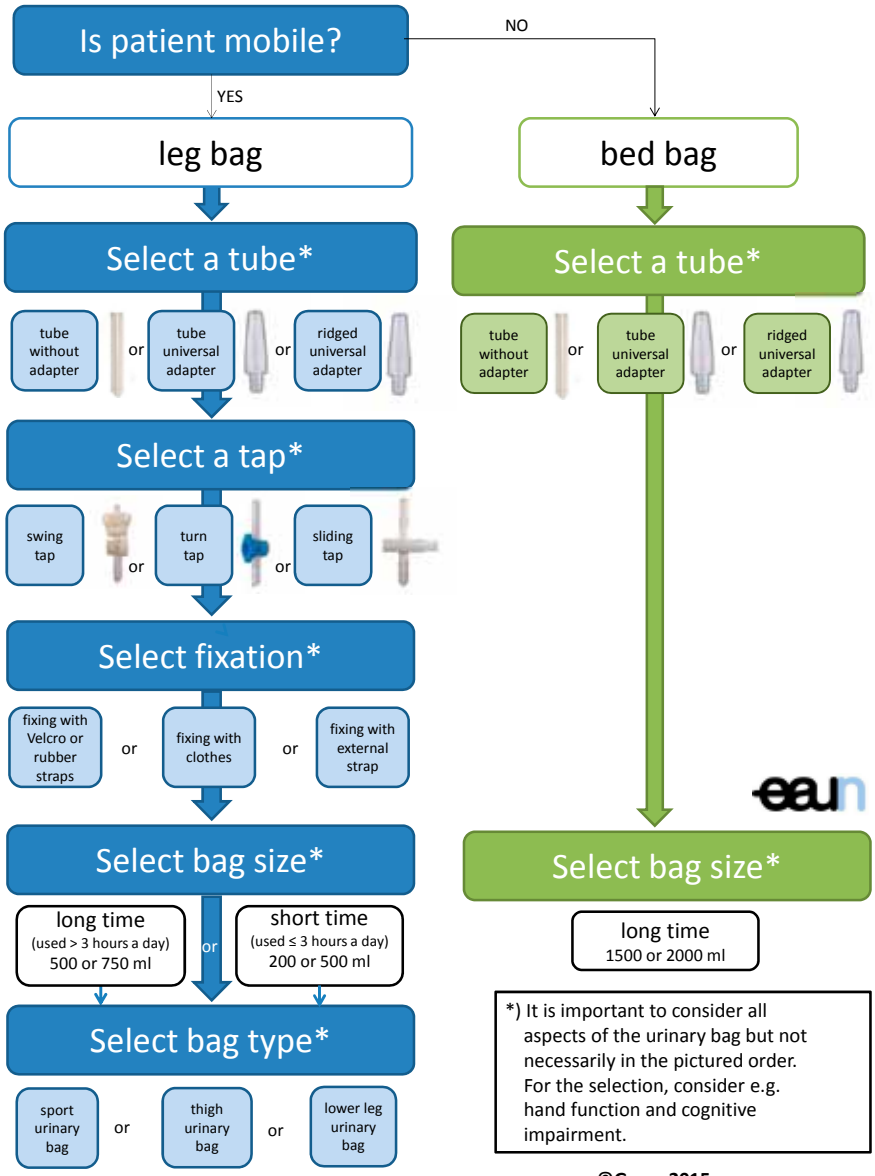
Most of the problems which occur using MEC are handling and instruction problems.

Problem	Possible reasons	Possible solutions
Pressure sore at the penis shaft	MEC is too small	Select a larger size MEC
	Pressure from the rim is too strong	Select a different product with shorter length
		Cut the rim with special scissors *Fig. 54 Cut the rim* *(Source: Manfred Sauer GmbH)* 
	Pressure from the adhesive stripe/tape is too strong	The adhesive stripe/ tape should not be glued in a circular pattern, but in a spiral pattern
Pressure sore at the foreskin	Pressure from the MEC is too high due to e.g. an erection	Unroll the urinary sheath 4-6 cm to ensure that there is sufficient space between the foreskin and the tip of the MEC
Leg bag drainage problems - disruption of urine flow	The MEC is trapped beneath the elastic trim of the under garment Clothing is too tight	Select more loose fitting clothes
	The tube is too long or kinked	Check the tube
	The leg bag is not secured properly	Check the leg bag for security and position
	The leg bag is not positioned correctly	Replace the drainage bag
	The leg bag contains air	
	The urine is cloudy	• Check for infection • Check fluid intake • Check pH of the urine

Leakage of the MEC	MEC does not fit well	Measure again and select the correct size
	The adhesive glue is not sufficiently effective	Use more adhesive glue Use a different brand of adhesive
	The adhesive and the MEC material are not compatible (glue does not stick to the catheter)	Use compatible material
	Technique used to apply adhesive is incorrect	Practise technique on a model first
	Hairs may be caught between the MEC and the skin - thereby producing small leakages	Remove the hair
The connecting tube keeps slipping away from the MEC		Choose compatible materials Roll the connecting tube a little further over the tip of the MEC for more security
Air in the urinary bag	Never allow air to enter the leg bag through the outlet tap	Always leave a small amount of urine in the bottom of the bag. This increases the suction in the system (creating a partial vacuum) which helps drainage and prevents build-up of urine in the buffer zone of the urinary sheath
Skin irritation or sores	Sensitivity / allergy to skin care products or material	Test an alternative product on a neutral area of skin; e.g. inside the wrist, to ensure there is no allergic reaction
	Prolonged use of adhesives	Replace MEC with one made of different material. Use a different brand of adhesive - before use, test on a neutral area of skin
	Talcum powder	Use MEC containing no talcum powder
Allergic skin reaction	Latex sensitivity or allergy	Use talcum powder-free MEC as well as latex-free MEC
Skin too damp	MEC was applied too soon after a bath or shower	Ideally, wait at least 15 minutes after a shower or a bath before applying the MEC
Skin abrasions, fungal infections		

Urinary tract infection	Check that urine can flow freely, tube is not kinked Do bladder scan to see if any residual urine	Patient education, inform on the mechanism of UTI development and provide clear instructions on the hygienic aspects involved in using MEC
	Low fluid intake	Increase fluid intake
	MEC replacement interval is more than 24 hours	Replace more often
MEC does not stay in place	Redundant or hyper-mobile prepuce	After consultation with a doctor and the patient, circumcision may be a consideration (will apply to long-term usage)

Appendix D. Flowchart MEC - Urinary bag decision tree



Figs. 32. Tube without adapter, 33. Tube with universal adapter, 34. Tube with rigid universal adapter and Figs. 35. Swing tap, 36. Turn tap, 37. Sliding tap

(Source: Manfred Sauer GmbH)

Appendix E. Voiding diary

Please inform the patients if they do not have to fill out all columns.

Voiding diary	
Name	
Date of birth	
Reason for catheterisation	
Frequency	
Catheter type	

Date	Time	Micturation in ml.	Residual volume in ml.	Urine loss yes/no	Problems e.g. leakage, pain, skin irritation, falling off

16. About the authors

Veronika Geng, RN MHSc/MNSc (DE), Chair

Registered Nurse, Infection Control Practitioner, Coach for Quality in healthcare, Master in health science specialisation in nursing.

Veronika Geng currently works as a project leader for the Manfred-Sauer-Foundation in Lobbach, Germany. She has performed clinical studies on the incidence of hospital-acquired UTIs. Veronika previously contributed, as a panel member, to guidelines on MECs and produced an instructional videotape on this topic.

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Hanny is a frequent speaker at national and international conferences and is involved in the national continence course for nurses in The Netherlands. In 2015, Hanny was involved in updating (in line with EAUN guidelines) a patient information booklet about clean intermittent catheterisation, including a protocol for nurses, in collaboration with the National Continence Nursing Society of the Netherlands.

Hanny is a member of National Urology Nursing Society (V&VN Urologie Verpleegkundigen), and the National Continence Nursing Society (CV&V). She is also a member of the National Stoma Nursing Society, a member of the ESPU-N (European Society for Paediatric Urology Nurses Group), and a member of the EAUN.

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Has worked for EAU since 2006. Was appointed coordinator for all EAUN activities in 2007. Assisted the EAUN Working Groups of all eight EAUN guidelines since 2007 with editorial work, finding the right illustrations, copyright issues, assisting with the literature search, data extraction and finding full-text papers, contributing to the design of clear flowcharts, and playing an important role in the planning and keeping of deadlines.

Hanneke is a member of the Guidelines International Network.

Ian Pearce (UK)

Ian has been a Consultant Urological Surgeon at Manchester Royal Infirmary, UK since 2002 having trained in Nottingham, Stoke and Greater Manchester.
He is currently the Honorary Treasurer Elect of the British Association of Urological Surgeons (BAUS) and the Editor in Chief of the Journal of Clinical Urology

Special interest: bladder dysfunction & andrology.

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