



The medical necessity and usage of a external urination device

Scope

With proper nutrition and hydration, the average human adult bladder¹ fills at a rate of two ounces per hour, involuntarily, and around-the-clock. A normal bladder can hold up to approximately two cups of water before it overflows. This means that adults need to use the bathroom about four to ten times a day² ideally before the bladder fills up and the pressure becomes unbearable. Diet, hydration, exercise, medication, disease state, and age regulate how fast a bladder fills up, and certain disease conditions especially those affecting the urinary tract could cause an increase or decrease in urine production. However, regardless of how much urine is produced, the bladder must be emptied several times a day to avoid infections that could potentially be life-threatening.

In normal circumstances, most adults can get to the toilet in enough time to urinate without peeing on themselves. However, women with age, limited mobility, post-operative patients, or degenerative diseases, even with perfect bladders, are sometimes unable to get to the toilet safely and on time. Ultimately, accidents happen that could lead to urinating on one's self; an experience that is not only embarrassing and depressing but can also affect her quality of life³.

1 "The Urinary Tract & How It Works" National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health. The NIDDK translates and disseminates research findings to increase knowledge and understanding about health and disease among patients, health professionals, and the public. Content produced by the NIDDK is carefully reviewed by NIDDK scientists and other experts. <https://www.niddk.nih.gov/health-information/urologic-diseases/urinary-tract-how-it-works>

2 "Urinary Frequency" Bladder and Bowel Community, Forward House, 17 High Street, Henley-in-Arden, B95 5AA, [bladderandbowel.org, https://www.bladderandbowel.org/bladder/bladder-conditions-and-symptoms/frequency/](https://www.bladderandbowel.org/bladder/bladder-conditions-and-symptoms/frequency/)

3 "Factors Affecting the Severity of Urinary Incontinence and the Quality of Life of Women With Urinary Incontinence" Hyun Soo Oh, Mi Kyung Kim, National Center for Biotechnology Information, 8600 Rockville Pike Bethesda, MD 20894, <https://pubmed.ncbi.nlm.nih.gov/16027498/>

urinary incontinence

An involuntary loss of urine that is a social or hygienic problem and is objectively demonstrable.

Certain medical histories affect how a person manages the process of urinating and when the bladder needs to be emptied. In some medical conditions such as urinary incontinence and overactive bladder, an increase in urine urgency or frequency can lead to voluntary and involuntary leaks. Factors such as older age, post-surgery, and existing degenerative diseases can affect mobility and make the process of getting to the bathroom and undressing quickly, a chore.

Causations, conditions and demographics for a urinary device

Urinary Incontinence

Leaking urine (urinary incontinence), which can result from sphincter dysfunction, is most often involuntary. According to the International Continence Society (ICS), urinary incontinence is an “involuntary loss of urine that is a social or hygienic problem and is objectively demonstrable.” It is estimated that about 50% of women will experience urinary incontinence in their lifetime and about 18% of the adult female population⁴ has urinary incontinence or urinate on themselves often. The prevalence increases with age from about 8% for women aged 30-39 and up to 33% of women aged 80-90 years, due to factors like aging, chronic disease, medications, multiple childbirth, and other relevant past medical history. Given that the elderly make up a good percentage of the population, many millions of women will pee on themselves, for several reasons, in their lifetime. Urinary incontinence can manifest as stress incontinence which is predictable, urge incontinence is unpredictable, or a mix of both, and can occur in varying degrees from a few droplets of urine to complete involuntary emptying of the bladder. It can happen a few times in a month or even a few times in a day, but regardless of how often it happens, urinary incontinence can be a source of anxiety and infections if not managed properly.

The elderly population as well as some young people, suffer from

4 “Urinary Incontinence in US Women, A Population-Based Study” Jennifer L. Melville, MD, MPH; Wayne Katon, MD; Kristin Delaney, MPH; et al, <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/486453?resultclick=1>

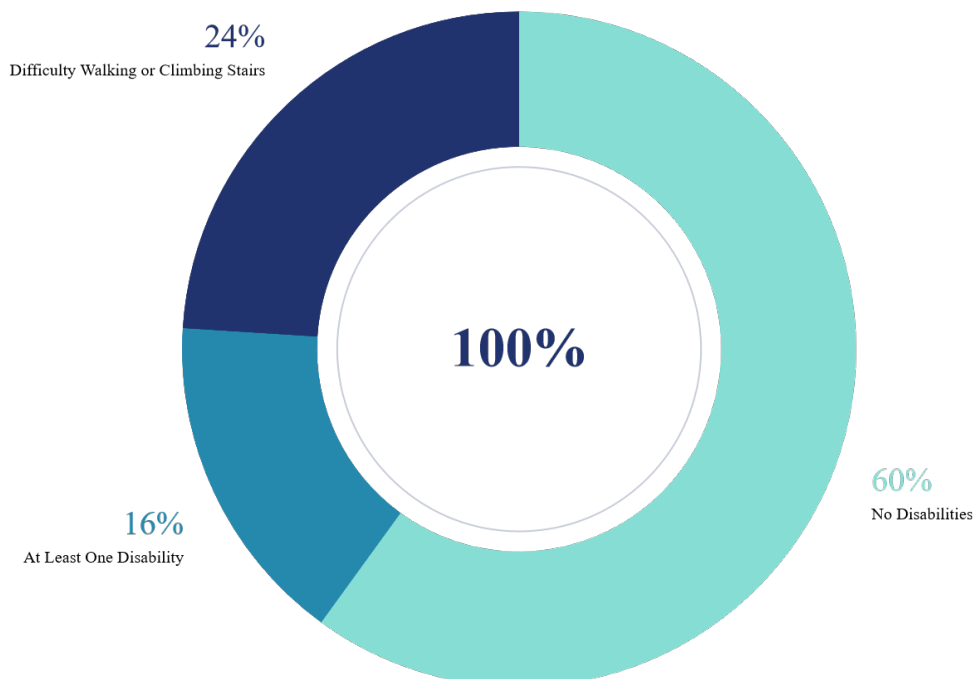
Overactive Bladder

The US census bureau estimates that about 40 percent of people 65 and older have at least one disability that reduces their mobility, and about 60 percent of this subset of people reported **difficulty with simple daily activities like walking and climbing stairs.**

overactive bladders that make it harder to get to the bathroom in enough time to avoid accidents. Overactive bladder⁵ (OAB) is a group of urinary symptoms that increases the urge and frequency of urination even when the bladder is not full thus leading to urine leaks. OAB can be caused by a variety of conditions including hormonal changes, urinary tract infection (UTI), pelvic weakness, diseases that affect the spinal cord, and neurological disorders that affect the signals between the bladder and the brain. About 40 percent of women in the United States suffer from one or more symptoms of overactive bladder and a great many do not seek medical attention. An overactive bladder can lead to isolation, depression, tiredness, poor sleep quality, infections, and an overall decreased quality of life. It can also affect relationships, work, exercise, and social life.

5 "What is Overactive Bladder (OAB)?" [https://www.urologyhealth.org/urologic-conditions/overactive-bladder-\(oab\)#:~:text=Overactive%20bladder%20\(OAB\)%20is%20the,when%20they%20feel%20this%20urge](https://www.urologyhealth.org/urologic-conditions/overactive-bladder-(oab)#:~:text=Overactive%20bladder%20(OAB)%20is%20the,when%20they%20feel%20this%20urge) Urology Care Foundation, 1000 Corporate Boulevard, Linthicum, MD 21090

Elderly Mobility and Disabilities



**Osteoarthritis (OA)
is the most common
joint disorder in the
United States.**

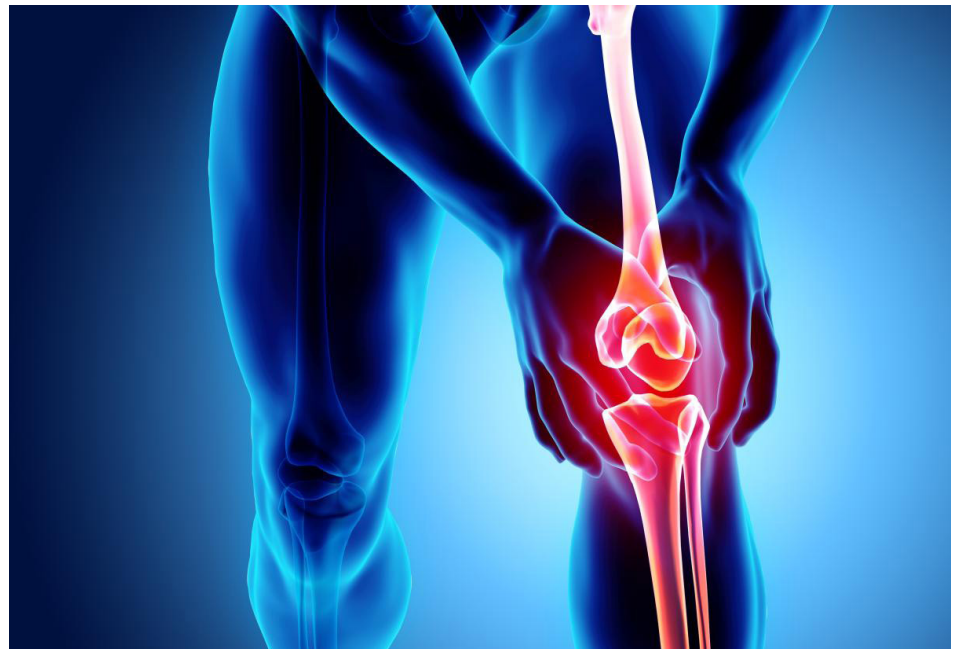
Among adults
60 years of age
or older the prevalence
of symptomatic knee
OA is approximately
10% in men
and 13% in women.¹

¹ “Epidemiology of
Osteoarthritis” Yuqing Zhang,
D.Sc¹ and Joanne M. Jordan, MD,
MPH² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920533/>

Elderly

Elderly women may have limited mobility as well as other existing chronic conditions that make a usually stress-free process like walking to the bathroom and undressing a challenging task. Navigating the bathroom for an elderly woman may also pose a risk of falls that could have devastating consequences. The US census bureau⁶ estimates that about 40 percent of people 65 and older have at least one disability that reduces their mobility, and about 60 percent of this subset of people reported difficulty with simple daily activities like walking and climbing stairs. These percentages represent millions of women who might sometimes need an alternative way to urinate other than the toilet.

⁶ “**Mobility is Most Common Disability Among Older Americans, Census Bureau Reports**” December 02, 2014 Release Number CB14-218, <https://www.census.gov/newsroom/press-releases/2014/cb14-218.html#:~:text=Nearly%2040%20percent%20of%20people,difficulty%20in%20walking%20or%20climbing>



Degenerative Bone Disease and Osteoarthritis

People with degenerative bone disease and osteoarthritis that affects the hands, feet, spine, hips, and knees, typically have a difficult time using the bathroom even with functional bladders. They frequently need help with undressing and squatting to urinate, and a trip to the bathroom is often a hassle.

Post-operative Patients

Patients who have recently had certain types of surgeries may also have problems with making it to the toilet as they may have restricted movement for their safety. Going to the bathroom on their own, or even with help can be tasking and sometimes unsafe. Some of these patients may be undergoing physical therapy for strength and eventually recover their ability for independent use of the bathroom but during their early post-op healing, movements like squatting in the bathroom can be painful and might be dangerous as well. A urinary device that is intuitive and easy to use is perfect for post-op patients with knee, back, hip, and plastic surgeries.

Centers for Disease Control and Prevention (CDC) estimates 234,000 non-fatal bathroom injuries were treated in U.S. emergency departments in 2008.

Of those bathroom injuries, 14.1% occurred when people stood up from, sat down on or were using the toilet.



It is estimated that up to 40 percent of women will have a UTI at some time in their lives.

Also called bladder infections or cystitis, a UTI occurs when bacteria enter the bladder, usually through the urethra (urine tube), and begin to multiply.¹

¹ “Urinary Tract Infections” University of San Francisco Health <https://www.ucsfhealth.org/conditions/urinary-tract-infections>

Current Treatment and Management Options

Urinary incontinence, overactive bladder, and accidental urination due to age and limited mobility are typically treated using lifestyle changes, behavioral modifications, drug interventions, and surgery which can be invasive. Some patients, however, will fail drug and behavioral therapy and even though catheterization might seem to be an option it carries a risk of chronic and serious UTIs in the long run. An external hypoallergenic urination device⁷ like The Tinkle Belle, eliminates the need to disrobe or squat, subsequently reducing the risk of injuries. It is appropriate and safe tool for women to direct the flow of urine and reduce trips to the toilet, while maintaining her quality of life and reducing the risk of falls.

⁷ “Incontinence Products and Devices for the Elderly”, Diane K Newman, <https://pubmed.ncbi.nlm.nih.gov/15446380/> National Center for Biotechnology Information, 8600 Rockville Pike Bethesda, MD 20894

External Urination Device: The Tinkle Belle

The Tinkle Belle is a portable device that gives females the freedom to urinate when needed even when not close to the toilet. We believe that females do not have to be limited to physical toilets when the urge to urinate hits, especially when they are unable to get to a toilet due to medical limitations. Many women, like the older woman, post-operative patient, or those with degenerative bone diseases mainly rely on absorbent pads, waterproof garments, and catheterization to manage their urinary incontinence. Even though these can help they are often not very discreet or comfortable. External urinary devices such as The Tinkle Belle are beneficial especially to post-op patients, patients with joint degeneration, and the elderly.

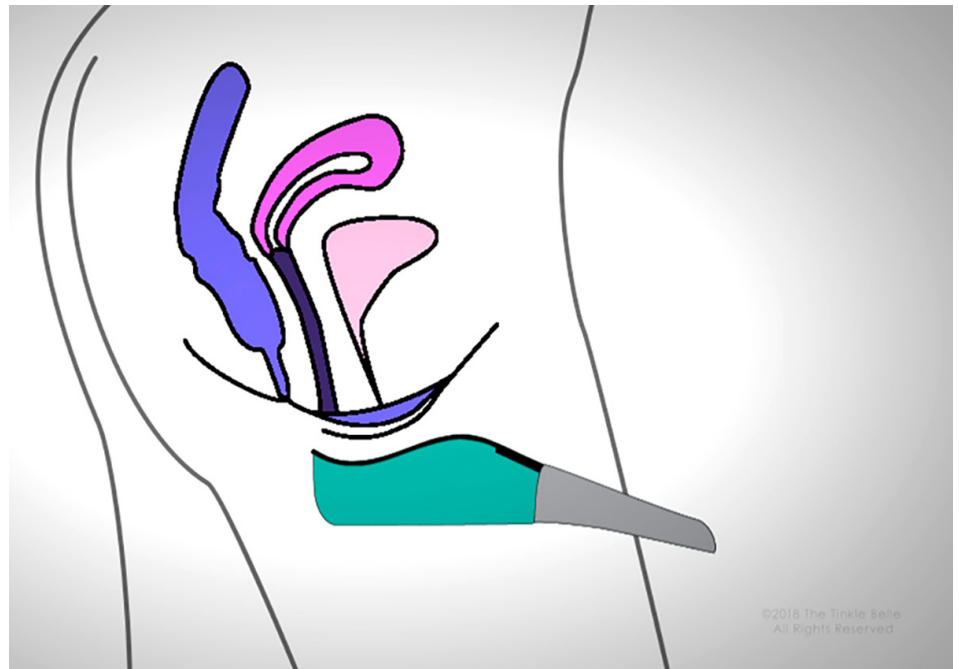


Why Use The Tinkle Belle?

Anatomical Fit – The Tinkle Belle is made for the shape and curve of the female anatomy to increase effectiveness, ease of use, and comfort during use. It really is as easy as sliding the device under garments, placing it in the right spot, and then urinating.

Leak Proof – The Tinkle Belle is leak-proof and will not collapse while using. This ensures that women can urinate without an embarrassing leaky mess that could damage the integrity of the skin and cause infections.

The Tinkle Belle
is made for
**the shape
and curve**
of the female
anatomy



Antimicrobial – One of the major medical concerns with urinary incontinence and utilization of pads is infections, especially on the skin. The Tinkle Belle is antimicrobial and can be used even without a tissue. This maintains the skin integrity of the patient and prevents unnecessary germs.

Hydrophobic and Hypoallergenic – Aside from being antimicrobial (won't grow bacteria), The Tinkle Belle is also hydrophobic (made to shed fluids) which allows it to draw fluid away from the body and eliminates the need for the use of toilet paper after urination. The Tinkle Belle is also hypoallergenic, so the user doesn't have to worry about getting an allergic reaction. It is BPA-free, silicone-free and latex-free.

**The Tinkle Belle is
ANTIMICROBIAL
and is easy to
wipe clean with a
disinfecting wipe,
tissue or clean water.**

It dries quickly from its
hydrophobic qualities
after a gentle shake.

Discreet – Due to its small size and weight, The Tinkle Belle is discreet so the user can urinate in comfort without the anxiety or fear of everyone knowing their medical condition or urinary limitations. It comes with a machine-washable stylish carrying pouch which helps to keep it even more discreet.

Portable, foldable, and compact – Most women who want The Tinkle Belle at home or on-the-move are already struggling with keeping up with their health, so a perfect device has to be easy to carry and store after use. The Tinkle Belle is compact as it measures 9.25 inches and weighs 1.8 oz (2.6 oz with our carrying case). When folded, it measures even smaller at 5.5 inches. The attached carrying pouch has a carabiner for additional carrying options.

Comfortable – Apart from being anatomically correct for the female, The Tinkle Belle is also designed for extra comfort by being soft and flexible, with a rounded edge for ease and comfort of wiping. It also has thumb rests for proper alignment and ease of use.

Long length – The Tinkle Belle is designed for every user especially those that need that extra length to point the device away from the clothing to avoid accidental splashes.

Appropriate for all ages and sizes – There is no age limit for the use of The Tinkle Belle. Females of any age and size can use The Tinkle Belle easily and comfortably. The Tinkle Belle shell can be compressed smaller or spread to open wider. Younger girls including post-operative young children, even though they might need adult help, can also benefit fully from using The Tinkle Belle.

Use it fully clothed – The Tinkle Belle is designed to be used without undressing, something that can be difficult for some women such as elderly patients, post-operative patients, and patients with degenerative bone disease.

Easy to clean – Unlike some hospital-grade urinary devices that might need sterilization after use, The Tinkle Belle is antimicrobial and is easy to wipe clean with a disinfecting wipe, tissue or clean water. It dries quickly from its hydrophobic qualities after a gentle shake, then stored until water and soap are accessible. It can be sanitized by utilizing the top rack of the dishwasher.



Easy to store at room temperature – Unlike large devices that take up a lot of space and need special storage conditions, The Tinkle Belle's compact size and material make it easy to store in any space and at room temperature for an extended period.

Reusable and Durable – The Tinkle Belle was designed for multiple-use making it more cost-effective than single-use devices. It is also made of a durable hard shell that not only catches more urine but also makes the device long-lasting.

Earth-friendly and UV stabilized - The Tinkle Belle is UV stabilized for outdoor use and is environmentally friendly. It is 100% recyclable. Every purchase of Tinkle Belle also supports orphanages that provide food, clothing, education, clean water, and shelter to children in developing countries.

Patented and Made in the USA – The Tinkle Belle is manufactured in the USA and is patented with US patents D842985S1 and 10568456B1 and EU patent 005509619-0001.

HSA and FSA eligible. Urological products are eligible for reimbursement with a flexible spending account (FSA), health savings account (HSA), or a health reimbursement arrangement (HRA). Urological products are commonly sold Over-the-Counter (OTC) at drugstores and medical supply stores, and are considered eligible for reimbursement with a consumer-directed healthcare account. The Tinkle Belle can be prescribed.

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