

# Improved Economic Costs and Effective Methods and Outcomes of Managing Urinary Incontinence with the URINCare® Bladder Management System

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## **Abstract**

Urinary incontinence remains an increasingly prevalent condition with significant associated morbidity. Among males specifically, detrusor dysfunction, sphincter dysfunction, iatrogenic causes as well as spinal cord injury represent conditions that rely upon presently inadequate means of external urinary collection. For both male and females, absorptive and condom catheter collection methods represent both inadequate and uncomfortable means in accomplishing dryness and protection of the patient. In addition, many men and women who are urinary incontinent commonly use commercially available adult diapers such as Depends or condom catheters with damaging adhesive properties. Absorptive products such as diapers, hold less than 250 cc of urine requiring frequent replacement, and Texas catheters can increase a patient's risk for penile erosion. Prolonged exposure to urine can cause skin irritation, skin breakdown, incontinence associated dermatitis, perineal fungal rashes, urinary tract infections (UTI), and may develop into more serious conditions such as decubitus ulcers. Technologic advances in pump dynamics as well as external collection designs now make it possible for this large group of patients to reintegrate without the problems of skin irritation and soiling so prevalent at this time.

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## ***Problems with Current Methods of Urinary Bladder Management: A Growing Concern***

Although studies have shown that catheters and diapers are adequate in managing incontinence, these bladder management options are not ideal; causing future problems such as UTIs, pressure sores, and urine associated contact dermatitis. The purpose of the URINCare® system is to create a dry perineal environment that would potentially decrease the maceration and excoriation associated with catheters, diapers, pads, and disposable absorbent incontinence products. Implementing a better system for managing urinary output could help eliminate the use and complications associated with these products. Using the URINCare® system over other bladder management systems will aid in keeping the patient dry, which may decrease the risk of developing diaper related decubitus ulcers, and will help maintain skin integrity for those with moderate to severe incontinence.

The presence of excessive moisture on the skin causes a reduction in skin hardness and temperature. These factors create a vulnerability to pressure induced blood flow reduction. Frequent washing and drying of the area causes chaffing near the perineal area. The presence of excessive moisture on the skin can result in maceration (over hydration) and also dryness and cracking once the lesions begin to resolve. All of these problems can increase an individual's risk of severe infection, leading to hospitalization.

## ***Eliminating Caregiver Strain***

Many caregivers struggle to provide alternative methods of bladder management and maintenance of moisture free skin for patients with incontinence and immobility. Caregivers have reported that the management of urinary incontinence in a nursing home setting is "difficult and time-consuming."<sup>1</sup> A resident's soiled garments should be changed and skin cleansed in a timely fashion. If an adult diaper is not changed regularly skin exposure to urine can produce a significant increase in skin wetness, with increased rubbing and abrasion predisposing the skin to breakdown. It is also important to note that the amount of time that is spent by informal caregivers (spouses, children, relatives) is a contributing factor to "caregiver burden." The time that is devoted to caring for individuals with urinary incontinence may be a factor in eventual nursing home placement. In a small study that was published in the Journal of Gerontology Nursing, "44% of caregivers indicated that their relative's loss of urine control contributed to the decision to institutionalize." Another study found that incontinence was a precipitating factor for 13% of 288 nursing home admissions.<sup>2</sup> The high prevalence of urinary incontinence in nursing homes suggests that managing this condition at home has increased potential to overwhelm informal caregivers.<sup>3</sup> If time spent managing individuals UI could be reduced by creating less caregiver strain with an easier UBM method, we would not only see improved patient care resulting in improved QOL, but also a reduced indirect cost to the

hospital. An alternative incontinence management product that will keep patients dry will eliminate their exposure to urine and potentially reduce the high cost of treating these incontinence-related skin disorders such as decubitus ulcers. Research and development of new and improved methods of UBM for this population should remain a priority.

**New methods for Bladder Relief**

Omni Medical is the first in introducing sensor activated pump driven technology that effectively pulls urine away from the body.

The URINCare® system (Figure 1) consists of 3 components: a urine collection device (EZ-LifeKup™ for males or the EZ-LifePad™ for females) the urinary pump (Control Device), and a reusable urinary drainage bag (EZ-LifeBag™). The flexible medical urethane EZ-LifeKup or EZ-LifePad contains urine sensors and serves as a reservoir for urine as it escapes from the bladder. The shape of the cup and pad comfortably fit the contours of the body, whether standing or sitting, and is worn discretely beneath the clothing. This device is applicable for any size male or female anatomy and is worn in conjunction with a specially designed undergarment.

The small lightweight control device monitors the urine sensor inside the cup or pad. When the sensor detects the presence of urine it activates the urinary pump which evacuates the fluid from the cup or pad at a rate of 1.3 Liters per minute. The Control Device uses a small, light rechargeable battery. Battery status indicators illustrate whether the battery is discharged, partially charged or fully charged. The user may manually control the system, at any time, by pressing the “M” push-button on the Control Device.

In laboratory tests conducted on a seated mannequin, liquid was successfully removed at a rate of 1.3 liters per minute with minimal residual moisture remaining in the bottom of the cup(less than 3cc) and no leakage outside the system. The URINCare® system is the result of improvements made to the currently fielded military Advanced Mission Extender Device (AMXD). The AMXD system is FDA approved, has successfully completed clinical trials approved by the Essex IRB and has successfully completed ground and flight trials with the Air Force Medical Review Board.

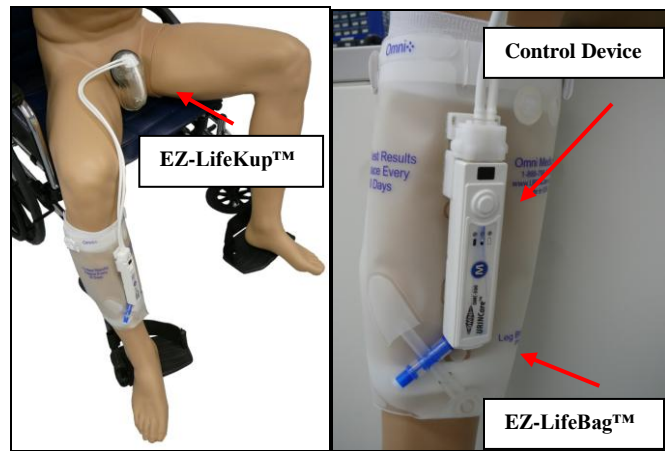


Figure 1

**Disposable Briefs/Absorbent Pads/Adult Diapers**

Decubitus ulcers, otherwise known as “pressure sores” are most frequently caused by moisture that is trapped against the skin by a diaper. Treating these pressure ulcers is costly; estimated at \$11 billion per year. <sup>4</sup> Of the 2.5 million incidents of pressure (decubitus) ulcers occurring in acute care hospitals, 62% of these decubitus ulcers occur over the sacrum, trochanter and ischium, all areas covered by a diaper, exposing skin to persistent moisture. In hospitals, the incidence of pressure ulcers ranged from 2.7% <sup>5</sup>to 29.5%. <sup>6</sup> Several subpopulations are at high risk:

- Quadriplegic patients (60%)<sup>5(ref)</sup>
- Elderly patients admitted for femoral fracture(66%)<sup>7(ref)</sup>
- Critical care patients (33%)<sup>8(ref)</sup>

**Cost Savings from Diaper/Pad Reduction in US Acute Care Hospitals**

<b>Cost of Treating Ulcers(billions, annually)</b>	\$11.0 <sup>4(ref)</sup>
<b>Proportion of Ulcers in Diaper Areas</b>	%62.0 <sup>9(ref)</sup>
<b>Cost to Treat Ulcers Caused by Diapers/Pads (billions, annually)</b>	\$6.8
<b>Proportion of Patients, Male</b>	%40 <sup>5</sup>

Figure 2

By using an external collection device for urinary incontinence management for male patients, hospitals can significantly reduce payor costs, and hospital days per patient while greatly improving the quality of care that is provided to these patients.

### **Clinical Trials and Case Reports**

A prospective clinical trial of 6 ambulatory patients and one patient with a spinal cord injury tested the Urincare system. A total of 364 applications of the device found that urine contact with the skin was completely eliminated. There were no reports of skin breakdown, perineal rashes, or irritation from the urethane cup. Average wear time was 8 hours per application and there were no infections or adverse events.

### **Conclusion**

#### *Improved Outcomes*

Utilizing a fully external continence collection device that has the capability of automatically sensing and evacuating urine away from the body has the potential to significantly reduce the risks of diaper associated pressure ulcers resulting from persistent moisture and skin breakdown and will ultimately result in better quality for the patient, and reduce indirect hospital costs for treating UI related complications.

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