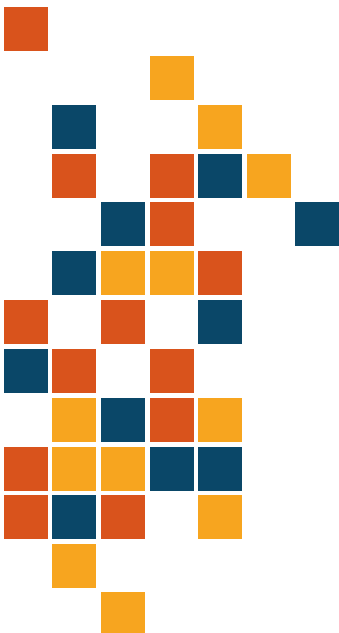


# EXECUTIVE SUMMARY

The United States (US) health care system is undergoing a significant shift from fee for service to pay for performance. Evidence-based decision making requires the health care provider to consider the individual patient's clinical circumstances and the state of the science to select the best choice. Evidence-based decision making for preventing hospital-acquired infections is complex and requires ongoing assessment of the state of the science and available evidence.

The goal of this white paper is to present the quantitative and qualitative evidence associated with the ReliaFit® Male Urinary Device and its documented benefits for decreasing the risk of catheter-associated urinary tract infection (CAUTI) by enhancing adherence to evidence-based recommendations, along with increased patient safety, decreased risks associated with urinary management, improved patient satisfaction, and decreased costs.



# HOSPITAL-ACQUIRED INFECTIONS: CATHETER-ASSOCIATED URINARY TRACT INFECTIONS

## Definition

The Centers for Disease Control and Prevention and National Health Safety Network (CDC/NHSN) define CAUTI as a symptomatic urinary tract infection or asymptomatic bacteremic urinary tract infection that occurs when a patient has an indwelling urinary catheter at the time of admission or within 48 hours before onset of the infection.<sup>1</sup>

## Public Health Burden

The public health burden associated with CAUTIs includes increased morbidity and mortality, longer length of hospital stay, and increased treatment costs.<sup>1,2</sup> Approximately 40% of all hospital-acquired infections are urinary tract infections (UTIs), and of these, 80% of patients have had indwelling catheters.<sup>3</sup> Patients who develop a CAUTI can develop multiple complications including urethritis, bladder obstruction, and UTI-associated sepsis.<sup>1</sup> Each episode of CAUTI is estimated to extend a patient's hospital stay by 0.4 to 2 days.<sup>1</sup> Excess costs associated with each CAUTI episode range from \$1006 to \$3803.<sup>1,4</sup> One of the major drivers for CAUTI prevention stems from the increasing prevalence of multidrug-resistant bacterial infections, overuse of antimicrobial therapy, and the need to eliminate unnecessary risk and promote antimicrobial stewardship.<sup>5,6</sup>

# EVIDENCE-BASED PREVENTION OF CAUTI

Microbes can enter the bladder in 1 of 2 ways, extraluminally or intraluminally.<sup>1</sup> Extraluminal contamination can take place during catheter insertion or by capillary action, and intraluminal contamination can take place via a break in a closed drainage tube or contamination of a collection bag.<sup>1</sup> Every day a patient has an inserted Foley catheter, his/her risk of bacteriuria increases 3% to 10%.<sup>3</sup>

Published guidance on the prevention of CAUTI requires a bundled approach for eliminating the known risks associated with indwelling urinary catheters, including reduction of urinary catheterization days and reducing the risk of biofilm formation and bacterial contamination.<sup>2</sup> Among the multiple evidence-based recommendations for CAUTI prevention, eliminating the risk associated with unnecessary indwelling urinary catheter days continues to be emphasized.<sup>2</sup> The preventive role of the ReliaFit® Male Urinary Device is centered on its use as an alternative to indwelling urinary catheters for urinary management in male patients who are appropriate candidates for external continence devices.

# RELIAFIT® EVIDENCE

## Safety and Efficacy

The ReliaFit® Male Urinary Device is a male external continence device that reduces the risk of CAUTIs, device leakage, and health care–acquired skin injuries. The ReliaFit® Male Urinary Device seal, flexible faceplates, and CathGrip® are all made from a hydrocolloid material. The ReliaFit® Male Urinary Device consists of the following components:

- One-size-fits-all flexible faceplate designed to be applied to varying types of male anatomy (eg, circumcised, uncircumcised, retracted) with a self-sealing vent to improve drainage
- Hydrocolloid seal that connects the device to the patient's anatomy
- CathGrip®, which secures urinary drainage tubing to the patient's leg
- Mastisol® Liquid Adhesive, a liquid adhesive that enhances device adhesion to the patient's skin, performing well in areas prone to moisture

The ReliaFit® Male Urinary Device has been found to be a safe and effective male external continence device when used in patients without urinary retention or bladder outlet obstruction.<sup>7</sup>

## Adherence to Evidence-Based Guidelines

Multiple evidence-based guidelines have been published regarding CAUTI prevention.<sup>2</sup> The CDC published a Category II recommendation in 2009 for CAUTI prevention, suggesting the consideration of “external catheters as an alternative to indwelling urethral catheters in cooperative male patients without urinary retention or bladder outlet obstruction.”<sup>8</sup>

The use of the noninvasive ReliaFit® Male Urinary Device may enhance adherence to evidence-based best practices for CAUTI prevention. Historically, condom catheters have been difficult to utilize effectively, with problems stemming from supply availability for correct anatomic sizing to difficulty of use on retracted male anatomy;<sup>9</sup> however, the novel design of the ReliaFit® Male Urinary Device allows for device application to varying types of male anatomy, prevents leakage, has an average wear time of approximately 24 hours, and reduces the risk of CAUTI development associated with invasive indwelling urinary catheters.

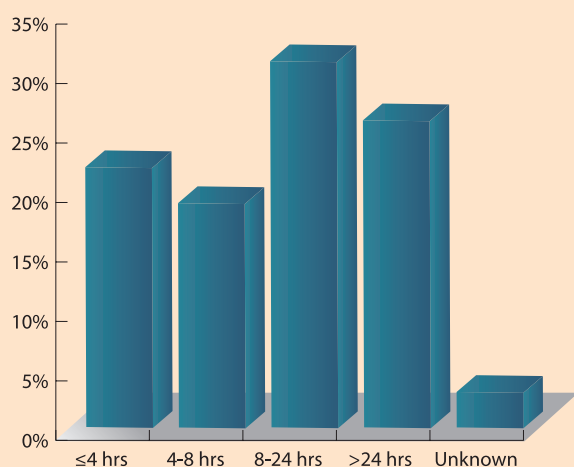
A small study was conducted with 20 patients who used 42 ReliaFit® Male Urinary Devices.<sup>7</sup> A total of 31 Registered Nurses responded to surveys regarding the effectiveness of the device. The findings of this study revealed the following:

- Mean wear time was >23 hours.
- The device was easy to apply compared to condom catheters.
- A total of 72.8% of the nurses said that they would recommend use of the device for routine management of men who required urinary management and met appropriateness criteria.

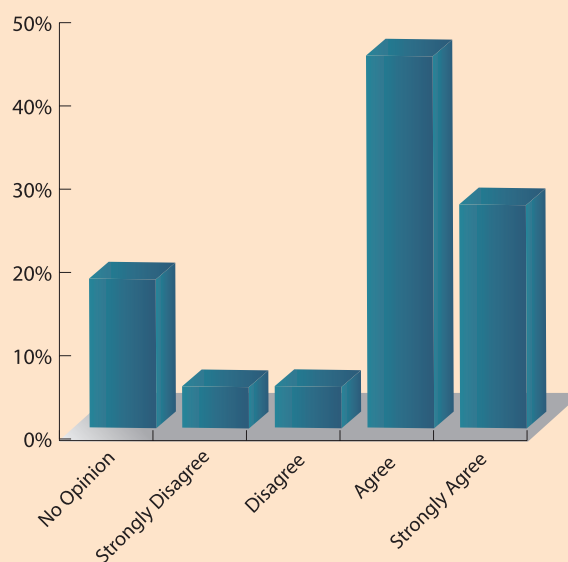
**Fig. 4: Rationale for Device Preference by RN**

ATTRIBUTE	ALTERNATIVE MALE URINARY CATHETER DEVICE	NO PREFERENCE	CONDOM CATHETER
Easy to apply	59.1%	22.7%	18.2%
Satisfactory urine flow	50.0%	40.9%	9.1%
Stays on securely	45.5%	50.0%	4.5%
No urine leakage	45.5%	40.9%	13.6%
Wear time	40.9%	50.0%	9.1%
Does not cause skin redness/irritation	40.9%	50.0%	9.1%
Patient comfort	36.4%	59.1%	4.5%
Patient acceptance	31.8%	68.2%	0.0%

**Fig.3: Wear Time Despite Some Premature Removals (n=42 applications)**



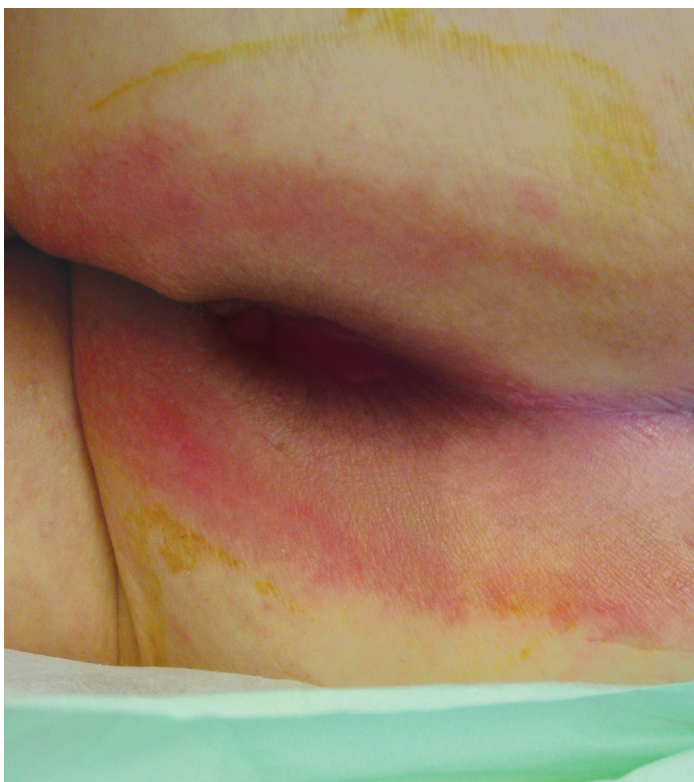
**Fig.5: RNs Likely to Advocate for New Device**



## Decreased Risk of Moisture-Associated Skin Damage

Moisture-associated skin damage is a condition involving “inflammation of the skin, occurring with or without erosion or secondary cutaneous infection.”<sup>10</sup> Incontinence-associated dermatitis is a form of moisture-associated skin damage that results from chronic exposure to urine or feces and is associated with increased risk of pressure ulcer development, significant pain, and decreased quality of life.<sup>10</sup>

The use of the ReliaFit® Male Urinary Device is a viable option for male urinary management, which ensures a secure fit without leakage. The design of the device prevents exposure of the skin to incontinence materials, thereby protecting the integrity of the skin and reducing the risk for incontinence-associated dermatitis.



## Improved Patient Satisfaction

The insertion of an indwelling urinary catheter can be associated with significant pain and discomfort, as well as urethral trauma.<sup>9</sup> Men who are appropriate candidates for the ReliaFit® Male Urinary Device may experience increased satisfaction with noninvasive urinary management alternatives.

### *Patients in the following clinical circumstances may benefit from the ReliaFit® Male Urinary Device<sup>11</sup>:*

- During surgery of short duration
- When strict intraoperative monitoring of urine output is not required
- Incontinence in the presence of open sacral or perineal wounds
- Palliative care
- Patients known to be at increased risk of morbidity associated with catheterization

### *The following clinical scenarios are not recommended for use of the ReliaFit® Male Urinary Device<sup>11</sup>:*

- During the perioperative period for urologic surgery
- During the perioperative period for procedures that involve contiguous structures of the genitourinary tract
- Urinary retention or bladder outlet obstruction
- When strict or real-time measurement of urinary output is required

Interventions for improving patient satisfaction are an important focus in today's health care environment. As hospitals have shifted to the pay-for-performance model, the total performance score associated with value-based performance has become essential for hospital reimbursement.<sup>12</sup> The total performance score is based on quality criteria set by the Centers for Medicare and Medicaid Services each fiscal year, which are centered on clinical criteria and patient experience criteria.<sup>12</sup> The patient experience criteria assess patient satisfaction on multiple levels including an overall rating of perception of care.<sup>12</sup> The ReliaFit® Male Urinary Device is one of the evidence-based interventions available to help minimize unnecessary risks associated with indwelling urinary catheters, can provide a comfortable external urinary management option that maintains patient comfort and integrity, and may have a direct impact on patient perception of care. In turn, enhanced patient perception may lead to improvement in patient satisfaction scores on HCAHPS surveys.

## Decreased Costs

The cost avoidance associated with the ReliaFit® Male Urinary Device extends from the prevention of CAUTI and the potential for improved patient satisfaction, which may positively impact the value-based purchasing model and total performance score. The CDC published a report on economic outcomes and discussed direct, indirect, and intangible outcomes associated with hospital-acquired infections.<sup>4</sup> It is difficult to measure indirect and intangible cost savings as a result of preventing CAUTIs, but these should be taken into consideration when factoring in patient satisfaction. Cost avoidance associated with the ReliaFit® Male Urinary Device may include the following:

- Prevention of CAUTI (the CDC calculated per-patient costs associated with CAUTI ranging from \$862 to \$1007 per infection;<sup>4</sup> Saint and colleagues calculated per-episode costs associated with CAUTI ranging from \$980 to \$2900)<sup>9</sup>
- Improved patient satisfaction by avoiding unnecessary risk and discomfort associated with indwelling urinary catheters, potentially impacting the total performance score
- Indirect savings via prevention of short-term and long-term morbidity and mortality
- Intangible savings via psychologic cost savings
  - › Reduced patient anxiety by avoiding unnecessary procedures
  - › Reduced pain and suffering associated with nosocomial infections
  - › Increased comfort and dignity associated with ReliaFit® Male Urinary Device external urinary management

## CONCLUSIONS

This white paper has presented quantitative and qualitative evidence associated with the ReliaFit® Male Urinary Device. The safety and efficacy of the ReliaFit® Male Urinary Device has been well documented, and it should be considered an evidence-based tool for CAUTI prevention and the prevention of unnecessary procedures and risk exposure. Utilization of the ReliaFit® Male Urinary Device may help enhance adherence to evidence-based best practices. The adherence to best practices for the prevention of CAUTI has multiple benefits, which include improved patient safety, satisfaction, and value of care.

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ReliaFit® is an essential product in the Eloquest Healthcare® portfolio.