

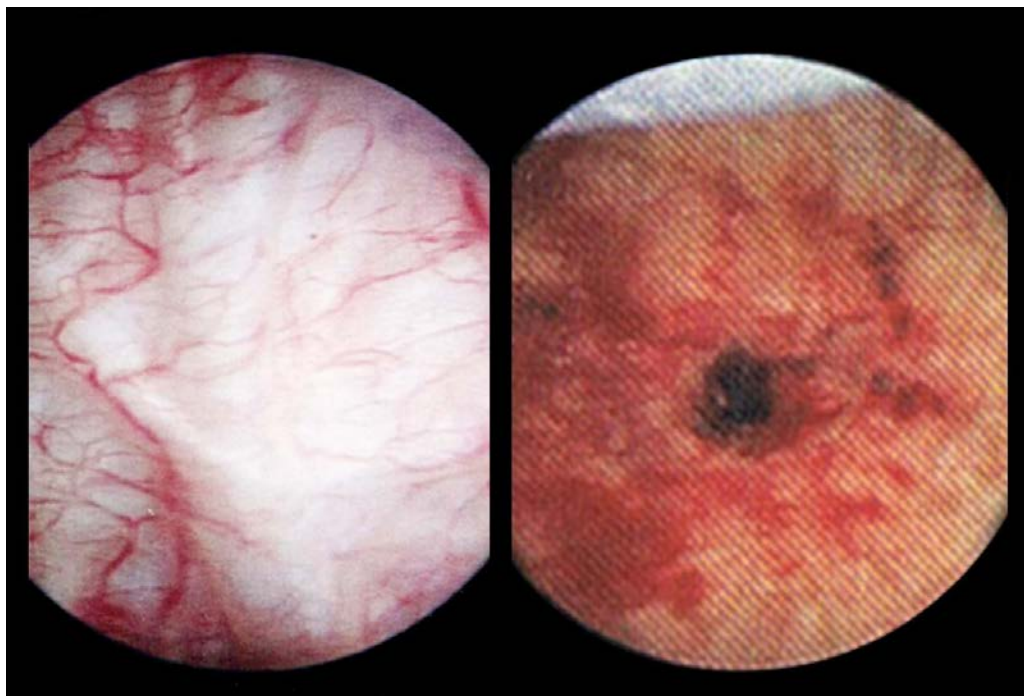
# How Foley Catheter Design Flaws May Lead to CAUTIs

The Problem...and a Potential Solution

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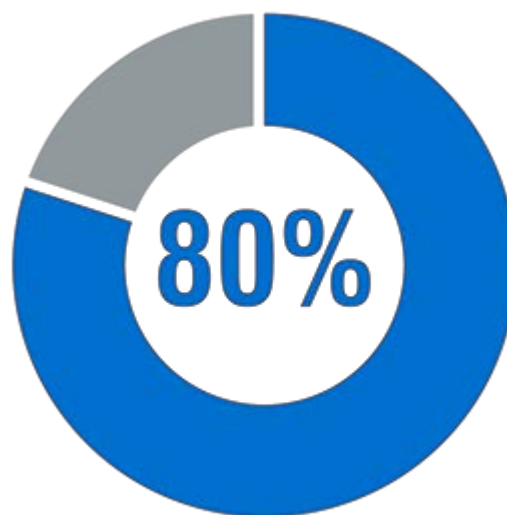
A non-catheterized bladder with a healthy mucosa exhibits no signs of trauma.

A catheterized bladder exhibiting trauma caused by the Foley catheter tip.

This document outlines a new national survey on clinicians' attitudes about catheter-associated urinary tract infections (CAUTIs). It also provides an overview of CAUTI-related challenges, and it suggests solutions to this vexing and prevalent infection risk.

Among key findings of the [survey](#) of infection preventionists and other clinicians:

- Most clinicians say their hospital administration is putting “strong emphasis on CAUTI reduction.”
- A majority are concerned that their hospital’s nurses don’t adequately comply with CAUTI protocols.
- Nearly 80% think Foley catheters can cause trauma to the wall/lining of the bladder.
- More than 80% say trauma to the bladder wall/lining increases CAUTI risk.



Percentage who say Foley catheters can cause trauma that increases CAUTI risk

These are important findings that have significant implications for clinical practice. Indwelling urinary catheters are widely used in healthcare, but they are also associated with numerous complications, including CAUTIs. Many of these complications are serious and some can be fatal. CAUTIs alone lead to an attributable 13,000 deaths<sup>1</sup> annually in the U.S.



Complications from urinary catheterization are also costly. Expenses include treatment costs, extended hospital stays, and use of physician and nursing time. Many sources place the per-incident cost for CAUTIs in the range of \$900 to \$1,000.<sup>2</sup> A leading organization of infection prevention experts (APIC) places the cost at about \$5900 per incident and overall US cost at more than \$3 billion annually.<sup>3</sup> One multi-site healthcare system, in a published analysis, calculated its per-incident cost to be about \$15,800, with only about \$4,400 of that reimbursed on average.<sup>4</sup>

Increasingly, hospitals are bearing the entire cost for CAUTIs. That is because Medicare and Medicaid no longer reimburse for the infections and many private insurers have followed suit. Meanwhile, the Affordable Care Act penalizes hospitals for high CAUTI rates.

# \$1000+ Average CAUTI Cost      \$400+ Million Cost to Health Care<sup>5</sup>

Infections and other complications of Foley catheter use can sometimes be prevented by certain precautions. These include:

- Using the catheter only when clinically indicated
- Leaving the catheter in place only as long as necessary
- Enforcing safe standards for catheter insertion and maintenance, and
- Using alternatives where possible.

Many of the complications associated with urinary catheterization are due to inherent flaws in the design of the most commonly used urinary catheter -- the so-called Foley. The catheter was first introduced in 1937 and has not been fundamentally modified since. Extensive research has shown how the catheter's design interferes with the bladder's natural defenses against infection.



Duette Catheter

The bladder protects against infection with a mucosal lining that prevents bacteria from adhering to the bladder wall and forming colonies. But the Foley catheter breaks down this defense in multiple ways.

When urinary catheterization is clinically indicated, it may be preferable to use the *Duette™*, a newly available device that addresses shortcomings of the Foley catheter. The new catheter, which has seen early clinical success in reducing CAUTIs, is described below.



Foley Catheter

# How Complications of Foley Catheterization Occur

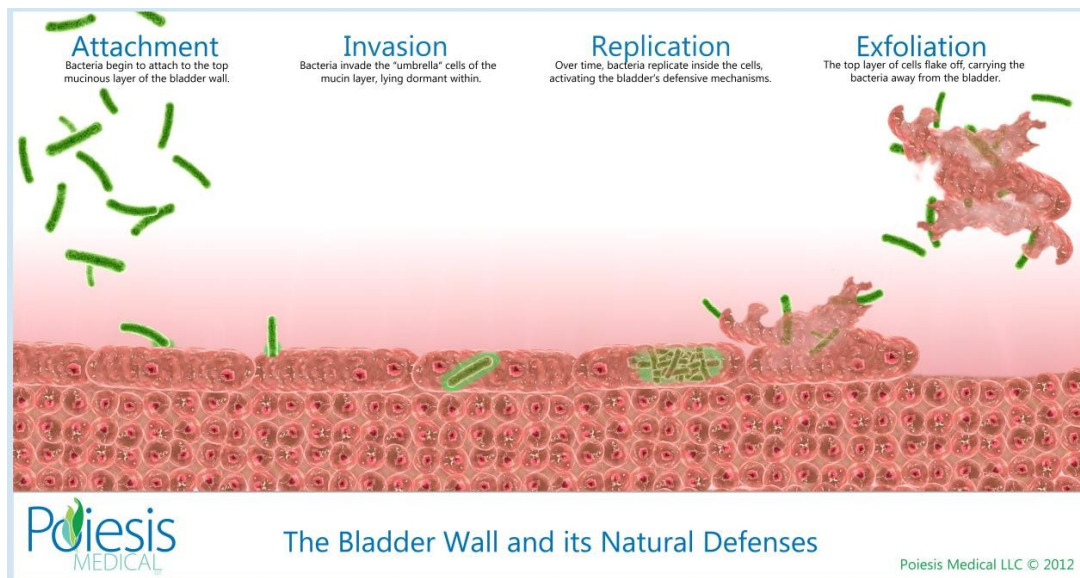
While Foley catheters provide crucial clinical benefits for appropriate patients, they are also one of the leading causes of nosocomial infections in the intensive care unit (ICU).<sup>6</sup> To understand how Foley catheterization itself leads to complications like CAUTI, one must appreciate the body's own means of preventing urinary tract infections – and how Foley catheters break down those defenses.

The bladder has two natural defense mechanisms: urination and the bladder's mucosal lining. Here's how the bladder's own protections work:

- Urination removes 99.9% of bacteria from the bladder. The remaining 0.1% is sufficient to cause an infection, however.
- The mucosal lining defends against these remaining bacteria by acting as a barrier to bacterial adherence.<sup>7, 8</sup> It is important to prevent adherence because if bacteria are able to attach to the bladder wall, they can form colonies. The colonies then form the basis for infection.

Meanwhile, new facet cells are growing continually to replace the ones that are exfoliated.<sup>7, 8</sup> If this layer of facet cells is damaged, then the sequence of adherence, colonization, and infection can follow.<sup>9</sup>

These images illustrate the process by which a healthy bladder's mucosal lining prevents infection.



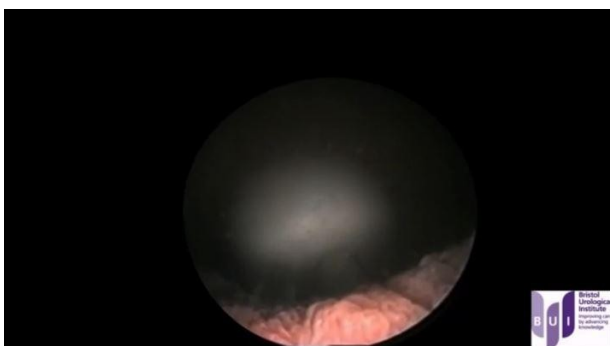
The natural defensive structure of the bladder wall works very well – but it was “built” to fight bacteria, not withstand assaults from a mechanical device. Unfortunately, the bladder’s defense mechanisms were not fully understood when the Foley catheter was developed in 1937. Thus, a catheter was created that violates the transitional cell lining, directly causing infection and other complications.

The Foley catheter breaches the wall’s defenses in several ways:

- **Pressure damage from catheter tip.** As the bladder drains, it collapses around the tip of the Foley catheter. Most of the pressure created as the bladder pushes against the tip is focused on a small area of the bladder wall. The pressure of the tip pressed against the bladder wall, combined with motion friction, can strip away the protective mucosal lining.<sup>10, 11, 12, 13</sup>
- **The trauma caused by tip pressure can lead to bladder spasms.** These spasms can then disturb the position of the anchor balloon, allowing bacteria to flow into the bladder. The trauma and greater presence of bacteria increase the risk of bacterial attachment and proliferation.
- **Suction aspiration damage from drainage eyes.** The bladder wall can wrap around the catheter tube and be aspirated into its exposed drainage eyes. This suction strips away the bladder’s protective lining and blocks urine from draining through the catheter.<sup>10, 11, 12, 13</sup>



The Foley Catheter damages the bladder mucosa with its tip and exposed drainage eyes.

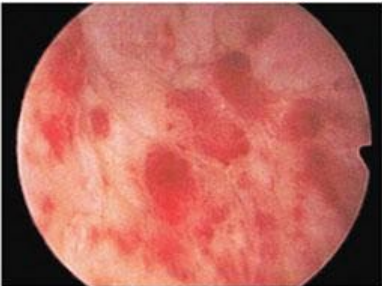


Video and still photographs showing tip and aspiration injuries caused by the traditional Foley catheter inside the bladder. Narrated by Roger Feneley, MD, of the Bristol Urological Institute. ([Click to view the video](#))

# Visual Evidence: How Foley Catheterization Harms the Bladder

These photos, taken using a cystoscope, document both tip and aspiration damage to the bladder caused by Foley catheterization. All photos were taken just 24 to 72 hours after catheterization. Compare the six photos below to the photo of the healthy bladder to the left.

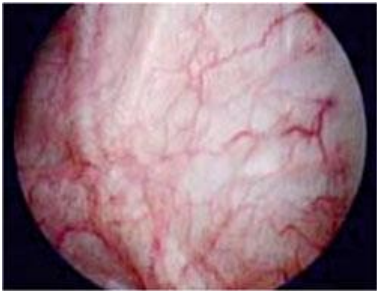
“We all know that a healthier, less traumatized tissue will probably be more able to resist clinical infection when exposed to bacteria as compared to a more diseased and less healthy tissue.”  
-- Rabih Darouiche, MD, Baylor College of Medicine. <sup>14</sup>



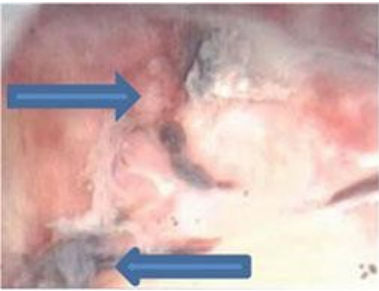
Bladder Wall Damage



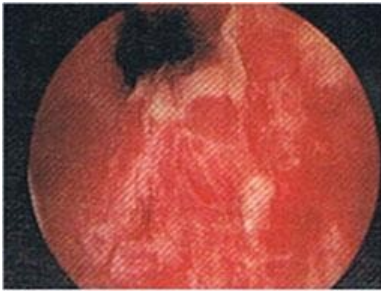
Polypoid Cystitis



A non-catheterized bladder with a healthy mucosa exhibits no signs of trauma.



Hemorrhage



Tip Damage



Tip Damage



Bladder Wall Trauma

# Promising Replacement for Foley Catheter

A new device designed to replace the Foley catheter (*Duette* Urinary Drainage System, Poiesis Medical LLC in Jupiter, Fla.) substantially satisfies the criteria outlined in the previous section for an improved indwelling urinary catheter:



The catheter has two balloons instead of the single balloon of the Foley device. The tip is enclosed in the second balloon, which serves as a cushion to prevent damage to the mucosal lining and bladder wall. In other words, there is no exposed tip to cause the tip pressure damage that is commonplace with Foley catheters.

The *Duette* Catheter. The distal balloon inflation port is always black, while the proximal balloon inflation port is colored by size.

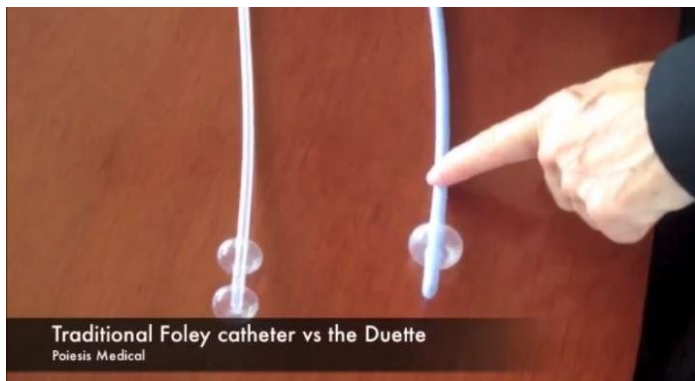
The drainage eyes are situated between the two balloons. This prevents the bladder wall from being aspirated into the eyes, thereby preventing the damage to the mucosal lining and wall from the resulting suction.

The device is inserted and removed like a standard Foley and therefore requires little new training of personnel.

The cost of the device is comparable to the price for 100% silicone Foley catheters, so there is no financial barrier to adoption for most facilities.

The *Duette* Catheter. The distal balloon inflation port is always black, while the proximal balloon inflation port is colored by size.

The *Duette* Urinary Drainage System is now in use in several dozen facilities. Initial clinical trials of the device have shown highly promising results, leading to substantial reductions in CAUTI rates.



Comparison of *Duette* Urinary Drainage System to traditional Foley catheter shows *Duette's* balloon and drainage eye features, which are designed to protect the bladder from injury. ([Click to watch video](#))

# References

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## About the Authors

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