Safety Foley Urinary Catheter

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Technology description

Background

A Foley catheter is a twin sterile tube inserted into the bladder for a period of time. It can also be called an in-dwelling catheter. It is held in place with a balloon at the end, which is filled with sterile water to prevent the catheter from being removed from the bladder. The urine drains through the catheter tube and into a bag.

Unlike most medical devices, urinary catheters are most commonly placed into and removed from patients by nurses, ancillary medical staff, and patients themselves. Unfortunately, incorrect handling and placement of urinary catheters can result in disastrous consequences, and physicians and non-physicians alike report frequent complications associated with placement and removal of urinary catheters. Indeed, urologists are regularly consulted to manage complications associated with misplacement of urinary catheters. A common complication is damage to the urethra (and extreme pain, if the patient is awake) when the balloon at the tip of the catheter is inflated (accidentally) while it resides in the urethra rather than in the bladder. This occurs when the person placing and inflating the catheter has not inserted it far enough through the urethra. This situation can create significant urethral injury, pain and bleeding, and typically necessitates a costly consultation by a surgical specialist. The catheter can usually be replaced after the injury, but may require invasive cystoscopy (placement of a small camera into the urethra). Invariably, in this situation, the catheter must remain indwelling for a longer than intended time period, to allow the urethra to heal and/or to provide pressure to halt the bleeding. Other consequences of intra-urethral balloon inflation are urinary tract obstruction, urinary tract infections, discomfort, renal failure, and death. The urethral injury may also result in urethral stricture or narrowing, which can necessitate additional costly surgical interventions.

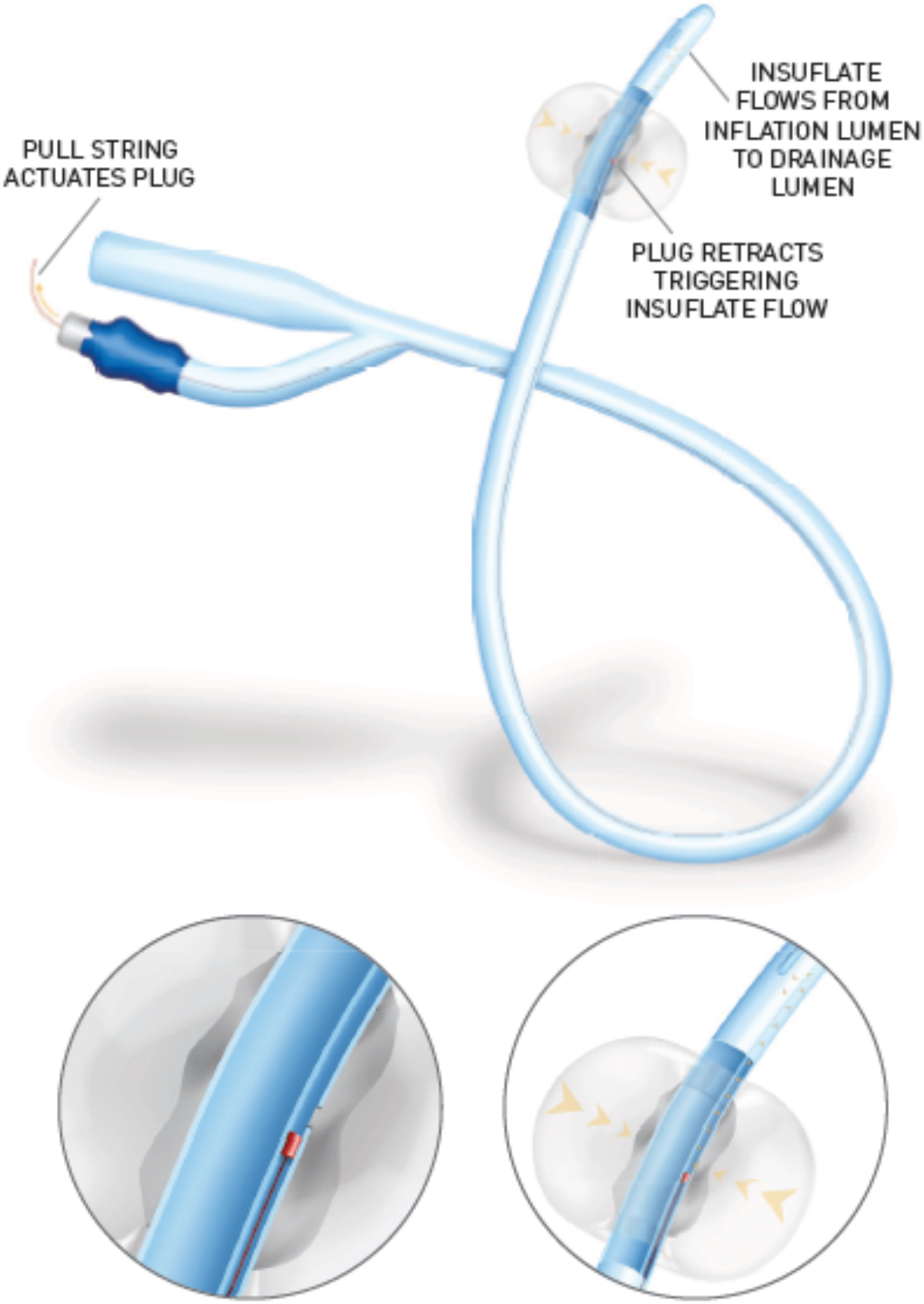
Another common complication associated with urinary catheters occurs when the catheter balloon bursts inside the patient's bladder. Balloon burst may occur for a variety of reasons, most commonly overfilling of the balloon or device malfunction (e.g., defective balloon). After balloon burst in the bladder, the catheter slides out of the urethra and must be replaced. More significantly, studies have shown that upon bursting, a fragment of the balloon wall frequently breaks away from the shaft of the catheter and remains within the bladder. The balloon fragment must be retrieved, e.g., by a surgical specialist with the aid of a cystoscope. If the fragment is not removed, the patient may have severe urinary symptoms, such as recurrent urinary tract infections and stone formation, which require further medical intervention and expense.

Another common failure of urinary catheters is a balloon that will not deflate. Current recommendations for managing a non-deflating balloon include percutaneous or endoscopic balloon puncture, instillation of chemicals to dissolve the balloon, or over-inflating the balloon to burst it. These techniques, while necessary, can result in balloon fragmentation, patient discomfort, bleeding, and damage to nearby organs.

Yet another complication occurs when a patient or healthcare professional attempts to remove the catheter, or the catheter is accidentally pulled out, while the balloon is still partially or completely inflated. For example the patient or healthcare professional might believe the balloon is deflated when it actually is not, the catheter tubing may snag on another object and get yanked out, a patient with altered mental status may pull out the inflated catheter, etc. The result of pulling out an inflated catheter is similar to that of inflating the balloon within the urethra, but typically more severe, because it may damage the entire length of the urethra. Further complicating premature catheter removal is the necessity to replace the catheter through an already damaged urethra, and possible disruption in some cases of a still healing surgical repair (i.e., after removal of the prostate for cancer or repair of a urethral stricture).

Technology Overview

Sanford Health has developed a Foley catheter that when elongated, automatically deflates. Disruption of the mucosal layer happens with a tensile force of around five pounds, and this device can be optimized such that the deflation happens at that force.



Application area

This device is intended to be used with in-dwelling Foley catheters with balloons. They can be used on patients with:

1. Severe urine retention or obstruction of urine outflow
2. Comfort for patients who are terminally ill
3. Non healing sacral, buttock, or perineal pressure injuries
4. Surgeries that are prolonged or on organs of the genitourinary tract

Advantages

1. Reduction in urethral injury complications
2. Reduction in complication related costs
3. Can deflate if the traditional valve fails.

Institution

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