

THE EFFECT OF ACCIDENTAL PULL OF THE FOLEY CATHETER WITH THE BALLOON FULLY INFLATED

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ABSTRACT

Introduction and Objectives:

The design of the standard urinary Foley catheter (FC) has several limitations due to the presence of a balloon. In addition to trauma (inflation in the urethra during placement or accidental removal), the FC has also been associated with some degree of residual urine, which contributes to increased risk of urinary tract infections. The Standard Performance Specification for the Foley Catheter (ASTM) is the basis for an FDA approval of intricate devices. In this Standard the responsibility for the safety of the use of the Foley Catheter is the primary of the Healthcare provider. ASTM stated regarding the use of Foley Balloon Catheter: " This Standard does not purport to address all the safety concerns associated with its use. It is the responsibility of the user of this Standard to establish the appropriate safety and health practices". The responsibility points out specifically to the Healthcare provider".

It is not uncommon for a patient recovering from anesthesia, heavy sedation, or individuals with cognitive deficit to forcefully pull out a Foley catheter with the balloon fully inflated. Improper removal of a Foley catheter may cause permanent and debilitating damage to the patient. The Foley catheter utilizes a balloon filled with sterile water as the retaining mechanism; however, fluid is incompressible. In addition, the weight of the Foley catheter balloon and the ever-present residual urine causes the patient to feel a continuous sensation to urinate. Residual urine induces the bladder to sustain periodic spasms causing patient discomfort and pain. While conscious and mentally capable patients are advised of the dangers of forceful Foley catheter removal, demented or heavily sedated patients are unaware of potential for permanent damage.

In obstetrics, females who pull out the Foley catheter with a fully inflated balloon run a high risk of developing permanent stress, urge, or total incontinence. Moreover, delirium occurs in 14-56% of elderly hospitalized patients, increasing the risk of traumatic Foley catheter removal. For at risk or confused patients, over inflation of the indwelling Foley catheter as it makes forceful removal more difficult.

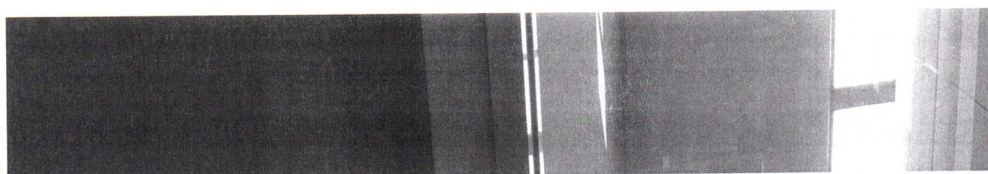
A bench study conducted in an laboratory of FDA registered, ISO 9000 laboratory using ASTM Foley catheter performance specifications. The objective of the study is to measure the newtons applied to remove an inflated Foley catheter balloon

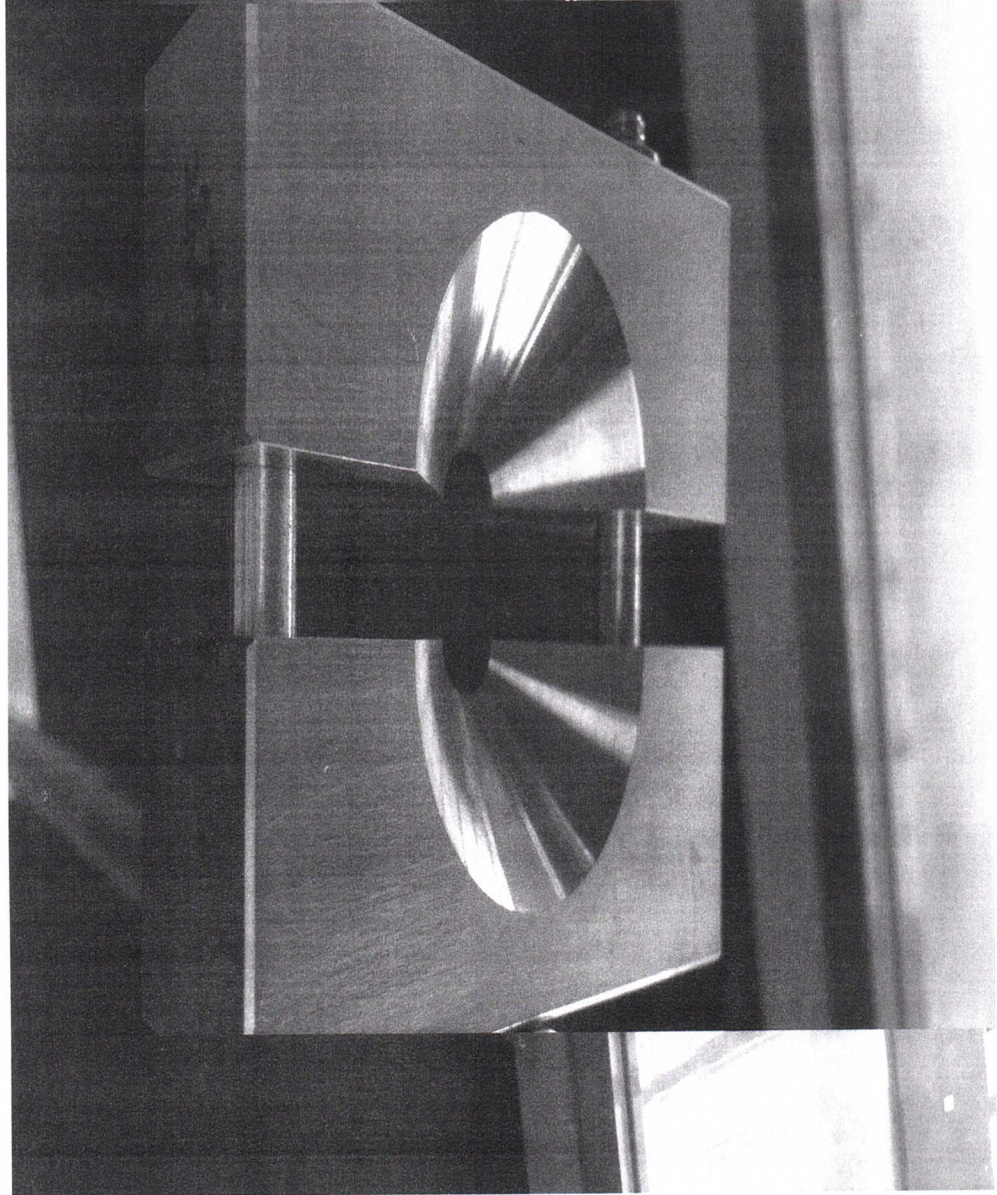
through a funnel-like apparatus in accordance with ASTM F623-99 section 4.3 *Inflated Balloon Response to Traction* and conducted with *Test Methods* in section 6. A 28 Fr funnel-like apparatus is used to represent the bladder outlet and urethra; the inflated Foley catheter balloon rests in the V-shaped portion of the funnel with the distal end of the catheter extended through the funnel barrel and hanging downward.

Method:

Ten individual samples of Six siliconized latex Foley catheter sizes 14F, 16F, 18F, 20F, 22F, and 24F are inserted through the aluminum funnel-like apparatus, inflated with 5cc, 10cc, 15cc, and 20cc of water, then attached to a calibrated digital force gauge measuring force in newtons with a $\pm 0.2\%$ accuracy. The force gauge measures the maximum force in newtons required to remove the inflated balloon from the funnel-like apparatus. The load is applied at a gradual speed of approximately X mm/minute.

Three samples of the Pure Silicone Foley Catheter were also tested. All balloon ruptured and the test was abandoned. A total of 63 Siliconized Foley Catheters were tested with different balloon size. The results measured in Newton Force and, also converted to Pounds. Individual samples of 10 siliconized latex Foley catheter sized 14Fr, 16Fr, 18







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until the balloon is pulled through the funnel.

Results:

French Size Inflation in CCs		Force in Newtons	Force in Pounds
14	5	28.2	6.33
14	10	40	8.99
14	15	47.7	10.56
14	15	39.9	8.97
14	15	39.0 (Balloon Rupture)	8.8
14	15	53.2	11.95
14	15	49.0	11.01
14	15	47.7	10.72
14	15	48.0	10.79
14	15	67.7	15.21
16	5	26.2	5.88
16	10	46.5	10.45
16	15	59.5	13.37
16	30	77.4	17.40
16	30	86.6	19.46
16	30	89.1	20.03
16	30	82.0	18.43
16	30	99.5	22.36
16	30	84.7 (Balloon Rupture)	19.04
16	30	74.8	16.81
18	5	23.1	5.19
18	10	51	11.46

18	15	85.4	18.97
18	30	103.1 (Balloon Rupture)	23.17
18	30	97.9	22.00
18	30	104.9	23.58
18	30	92.9	20.88
18	30	109.2	24.54
18	30	118.2	26.57
18	30	105.3	23.67
20	10	67.0	15.06
20	10	47.5	10.67
20	10	58.4 (Balloon Rupture)	13.12
20	10	47.8	10.74
20	10	63.3	14.23
20	10	61.7	13.87
20	10	53.8	12.09
20	10	60.7	13.64
20	10	65.0 (Balloon Rupture)	14.61
20	10	70.2	15.78
22	5	37.1	8.34
22	10	66.4	14.92
22	15	101.6	22.84
22	30	132.6	29.80
22	30	114.0	25.62
22	30	148.1	33.29
22	30	143.4	32.23
22	30	129.7	29.15
22	30	129.2	29.05
22	30	163.2	36.68
24	5	45.9	10.31
24	10	88.8	19.96
24	15	Balloon Rupture	N/A
24	30	187.8 (Balloon Rupture)	42.21
24	30	169.2	30.03
24	30	187.1	42.06
24	30	153.7 (Tube Malfunction)	34.55
24	30	161.7	36.35
24	30	200.7	45.11
24	30	201.2	45.23
26	5	32.3	7.26
26	10	79.8	17.93
26	15	117.1	26.32

Conclusion:

As the Foley catheter is retained in the bladder, a soft tissue cavity, the consequences of forcefully removing a fully inflated balloon in various sizes can cause serious bleeding, severe pain,, damaging, and even permanently debilitating for the patient. Recommendations to overinflate the balloon in delirious patients should be avoided as this increases the risk factors for severe injury to the bladder neck as well as the internal and external urinary sphincter mechanism. .

Orthopedic and Gynecological focused studies reveal ligament tears occur 88 newtons and soft tissue tears at 12 to 44 newtons.