



Ur24Technology

Introducing the first external catheter system actively emptying the bladder for men and women & pediatrics

Traditional Internal Catheters Put Patients at Risk

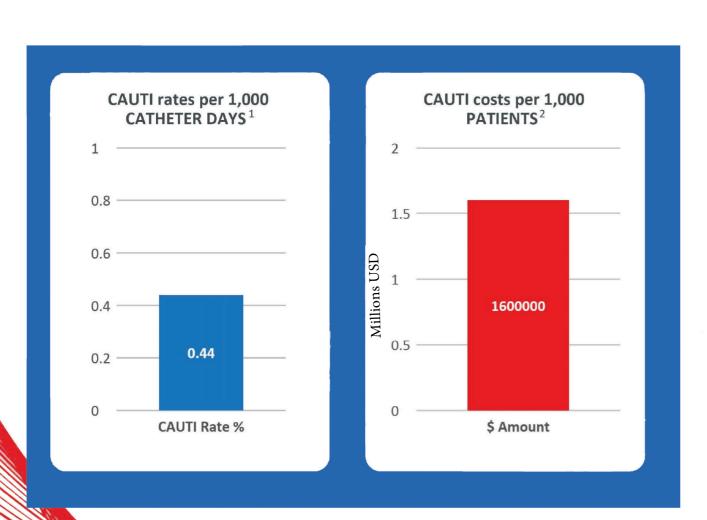
Internal catheters, which dominate acute and long-term care settings, are the #1 risk factor for developing catheter-associated urinary tract infections (CAUTIs)



- 1. National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure. https://www.hospitalsafetygrade.org/media/file/CAUTI.pdf accessed August 15, 2020
 - 2. Catheter-associated urinary tract infection. The Institute for Healthcare Improvement. http://www.ihi.org/Topics/CAUTI/Pages/default.aspx accessed August 15, 2020
 - 3. Antibiotic Resistance Threats in the United States 2019. https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf accessed August 15, 2020

CMS and Major Medical NOT reimbursing for CAUTIS

Most cases of CAUTI are preventable, and since October 2008, the Centers for Medicare & Medicaid Services will no longer reimburse costs associated with hospital-acquired CAUTI. In a study with the AHRQ, cases with CAUTI resulted in \$4,694 to \$29,743 in additional cost per patient.



COST OF CAUTIS

- Complications associated with CAUTI result in increased length of stay of 2-4 days, patient discomfort, and excess health care costs, and contribute to increased mortality.3
- The cost of a CAUTI can average over \$13,500. The way hospitals get dinged for this is that CMS and Major Medical does not reimburse for the cost.4
- The estimated total U.S. cost per year for CAUTIs is Over \$6.2 Billion.³

- 1. (https://www.hospitalsafetygrade.org/media/file/measure_sheet_CAUTI.pdf). Based on \$13,793 per patient
- 2. https://www.ahrq.gov/hai/pfp/haccost2017-results.html#cau
- 3. https://www.sciencedirect.com/science/article/abs/pii/S0196655318300361

TrueClr: A Revolutionary External Catheter to Eliminate CAUTIs for both adults and pediatrics

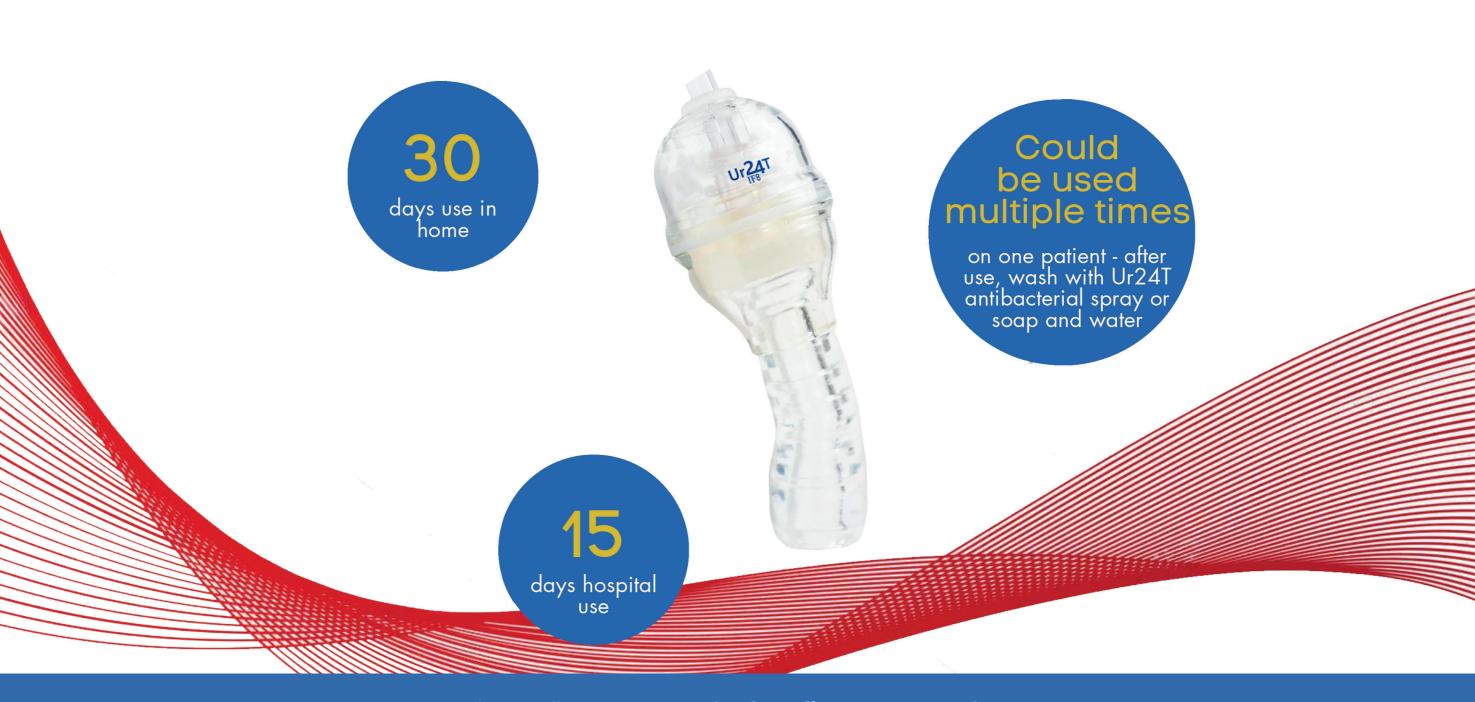
Introducing the TrueClr Portfolio, the world's first completely external catheter system designed to comfortably empty the bladder while eliminating CAUTIs.

- ✓ Non-invasive and non-adhesive
- Eliminates skin irritation and inflammation
- Latex-free and hypoallergenic
- Leak-proof design
- Easy-to-use, portable & reusable
- Made in USA



TrueClr is Reusable which equals cost saving benefits

Hospital 15 days reuse with cleaning at least every 48 hours. At home we guarantee 30 days of use.



TrueClr Adult Catheters



TrueClr Pediatric Catheters

Introducing the TrueClr Pediatric external catheters, the world's first completely external catheter system designed for pediatrics



FDA Approval Letter

FDA Class I Device

III Regulatory Classification

We reviewed FDA classification regulations relating to urinary catheters. The relevant regulations are found in 21 C.F.R. Part 876, "Gastroenterology-Urology Devices." Of the devices described under Part 876, the following appear to be the most relevant:

- 21 C.F.R. § 876.1800 Urine flow or volume measuring system
- 21 C.F.R. § 876.4370 Gastroenterology-urology evacuator
- 21 C.F.R. § 876.5130 Urological catheter and accessories
- 21 C.F.R. § 876.5140 Urethral insert with pump for bladder drainage
- 21 C.F.R. § 876.5250 Urine collector and accessories
- 21 C.F.R. § 876.5310 Nonimplanted, peripheral electrical continence device
- 21 C.F.R. § 876.5980 Gastrointestinal tube and accessories

SheppardMullin

Sheppard, Mullin, Richter 8, Hampton LL 2093 Pennsylvania Avenue, NW, Suite 1 Wasnington, Dr. 20006-6801 202747,1900 main 202747,1901 fax



MEMORANDUM

ATTORNEY-CLIENT PRIVILEGED & CONFIDENTIAL

To: Victoria Suarez Dat Ur24Technology, Chief Information Officer

Date. 20 July 2020

From: Allison Fulton
Partner, Sheppard Mullin Richter &
Hampton LLP

File Number: 71KK-310310

Re: Regulatory Analysis of Ur24T Urine Collection Device

I. Executive Summary

Ur 24Technology has developed an external urinary catheter and collection container for male and female patients (the "Ur24T Apparatus"). Based on a review of the product description and functionality on the Ur2Technology website, (<a href="https://lincommons.org/lincommons.o

II. Product Description

The Ur24T Apparatus comprises a polymeric tube and collection container that is capable of drawing urine from the urethra of males and females through the tube and into a collection container. The device mg/t_search with a standard aspirator pump. A description of the product, and a video of be_crowduct in use, can be found here [http://www.ur24techno.__com/].

Regulatory Classification

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SMRH:4847-8360-6723.1

accessorie

actor and accessories," appears to ories not intended to be connected vices (i.e., exempt from premarket sterile, it also is exempt from good t is below.

a device intended to collect a suitable receptacle, a means to prevent the of urine collectors are:

connected to an indwelling in kit and the closed urine

ed to be connected to an ber sheath, pediatric urine continence device, and the

nd accessories intended to exempt from the premarket thapter subject to 876.9.

ctor and accessories not device is exempt from the 807 of this chapter subject rotherwise represented as ig practice requirements of oter, with the exception of pring records and 820,198

otions from premarket notification. e description of the generic type of the trom premarket notification. For for a different medical purpose, or then the exemptions will not apply.

icluding requirements for GMP (as

. <u>Conclusion</u>

Based on product functionality and current labeling, the Ur24T Apparatus likely is a class 1, exempt device under 21 C.F.R. §876.5250. As a class 1 device, FDA's general controls apply. The device also will be exempt from GMP regulations if it is not labeled as sterile.

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Improving Patient Outcomes by Revolutionizing Care

TrueClr an innovative FDA Class I Device designed to actively eliminate contents of the bladder

| | TruClr | BD PureWick | Stryker Primofit | Coloplast Coveen |
|-----------------------------------|----------|----------------|---------------------|---------------------|
| Empties the Bladder Automatically | / | X | × | X |
| Use in Males | | X | | |
| Use in Females | / | / | X | X |
| Use in Pediatrics | | X | X | X |
| Portable | / | X | X | / |
| Avoids Urine to Skin Contact | | X | × | × |
| Non-Adhesive Application | / | / | × | X |

8 Hour Outpatient Study from UTHealth

Data Results from UTHealth Extended Clinical Trials.1



Patient: MALE

- 72 years old
- Urinary incontinence
- 12 Days of data:
 - 1. Duration from 7 to 9.5 hours
 - 2. Collection from 550 1050 ML
 - 3. Average collection of 647 ml/session.
- Comments: Comfortable. Amazing, urine collection system easy to use
- NPIAP Score = 0

NO EVIDENCE OF IRRITATION.
NO EVIDENCE OF REACTION OF ANY TYPE.



Patient: FEMALE

- 53 years old
- 11 Days of data
- NPIAP Score = 0



NO EVIDENCE OF IRRITATION.
NO EVIDENCE OF REACTION OF ANY TYPE.

Methods for Patients Data:

- 1. Tools:
 - a. National Pressure Injury Advisory Panel "NPIAP" Pressure Injury Stages b. Verified skin monitoring assessment
- 2. Photos randomized and reviewed in a blinded fashion
- 3. 2 independent evaluations:
 - a. Adult Dermatologists b. RN skin assessment expert

1. data on File: UTHealth, CaseStudy-DrJonMeliones Not actual patients shown





TrueClr Hospital Utilization: Intensive Care Units "ICU"

- Ability to decrease the use of Indwelling Catheters which decreases the opportunity for CAUTIs
- Ease of use to monitor intake and output (I&Os)





TrueClr Hospital Utilization: Intensive Care Units "ICU"

- Easier to Monitor I&Os
- Ease of use for both RNs and patients
- Decrease opportunities of patients acquiring UTIs with stagnant depends underwear.

TrueClr Hospital Utilization: Outpatient Surgical Centers

- Outpatient procedures
- Increase efficiency
- Decrease opportunities for Hospital Acquired Infections-CAUTIs
- Improved patient comfort
- Reduced trauma to urethra / bladder

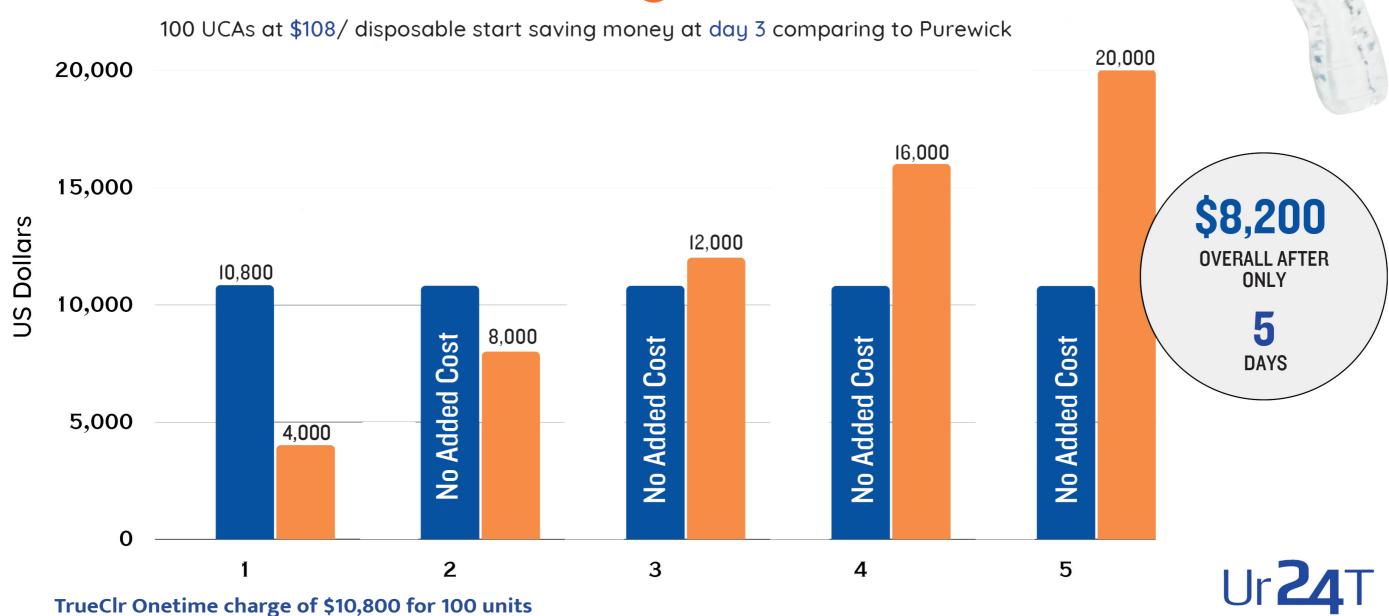




TrueClr: Value Proposition | 100 UCA at \$108 per unit

Ur24T recommends to clean catheter once every 48 hours in hospital
Guarantees 30 days if used at home



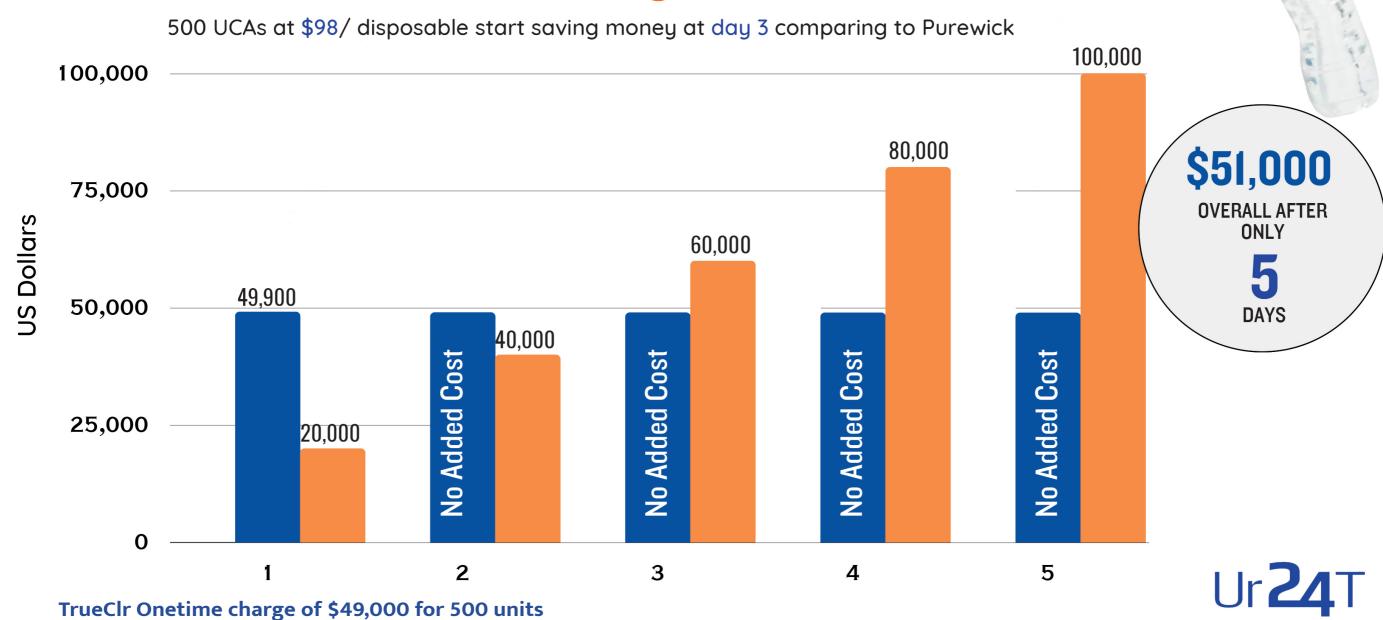


TrueClr: Value Proposition | 500 UCAs at \$98 per unit

Ur24T recommends to clean catheter once every 48 hours in hospital

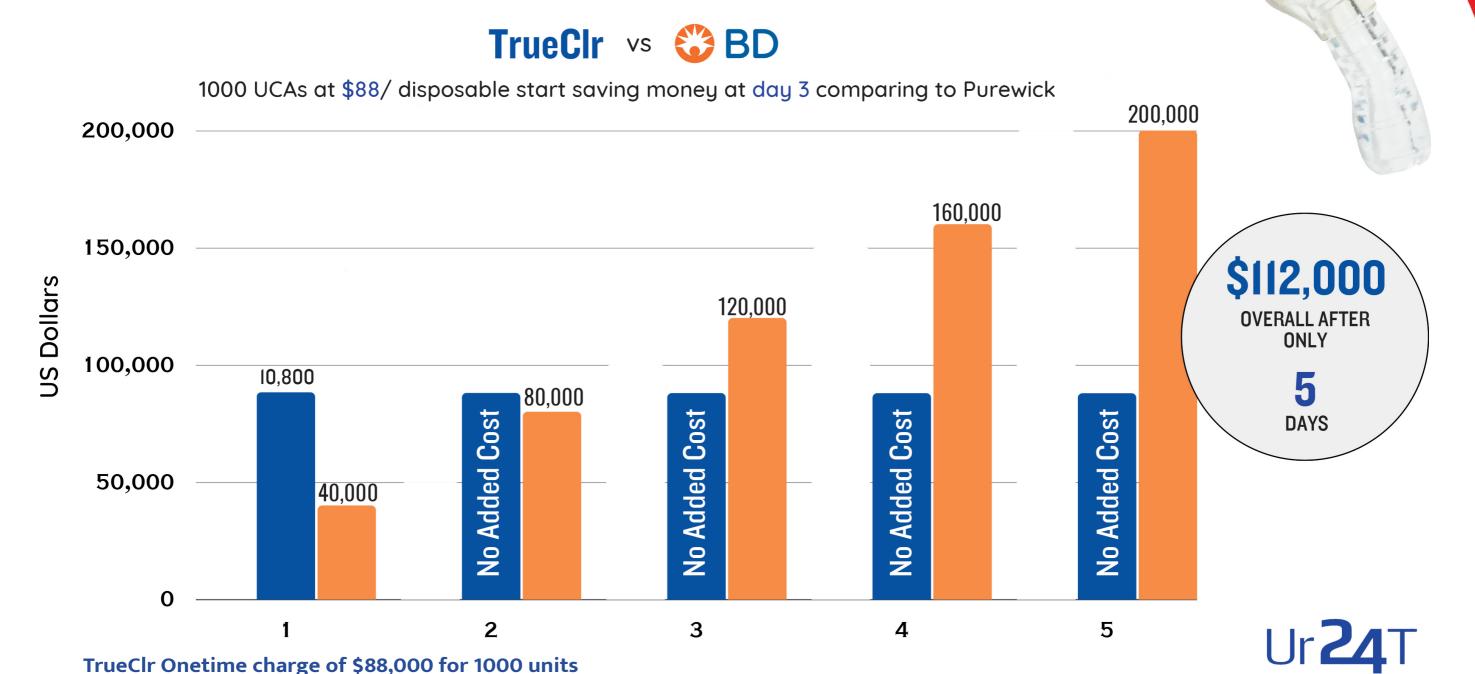
• Guarantees 30 days if used at home





TrueClr: Value Proposition | 1,000 UCAs at \$88 per unit

Ur24T recommends to clean catheter once every 48 hours in hospital
Guarantees 30 days if used at home





- Founded in 2000 and headquartered in Miami Lakes, Florida
- Proven, agile, flexible manufacture of Wound closure devices: Absorbable and non-absorbable surgical sutures, mesh, and bone wax for the cardiology, dental, and ophthalmology markets
- Distribution to over 130 countries
- Operates a state-of-the-art, ISO 13485-certified production facility in Florida over 500,000 sf including clean rooms and sterilization chambers
- Focused on operational excellence to meet highest health standards, holding certifications with-FDA, CE, ISO, MDSAP, and NIOSH, as well as country registrations all around the world
- Over 375 employee's full time



An Opportunity to Step Outside of Internal Catheters and Step Into the Future of External Catheter Systems

Ur 24 Technology

- FDA class 1 & CE mark
- Ur24T is ISO 13485 compliant
- Ur24T is Medicare Part B DME reimbursable
- Made in the USA





