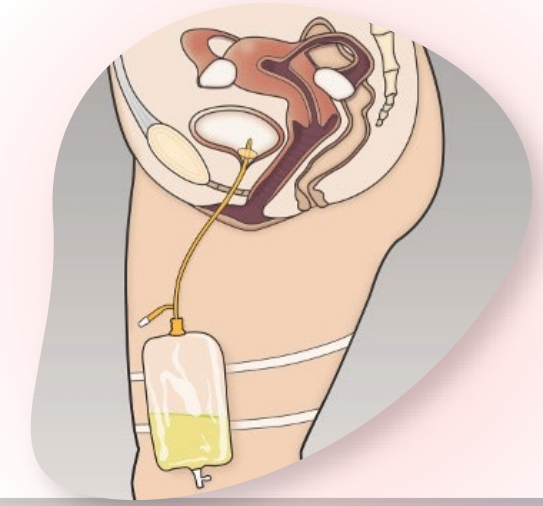
Ur24Technology®

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).

>13,000
deaths per year from internal catheters



Nearly 1 in 3
acute care hospital infections are caused by CAUTIs[1]

~449,334
CAUTI events occur per year in the US[1]

Over 2.8 million
antibiotic-resistant infections occur in the US each year[3]

80%
of all hospital-acquired urinary tract infections are a result of internal catheters[2]

#1 risk factor
for developing a CAUTI is prolonged use of a urinary catheter[2]

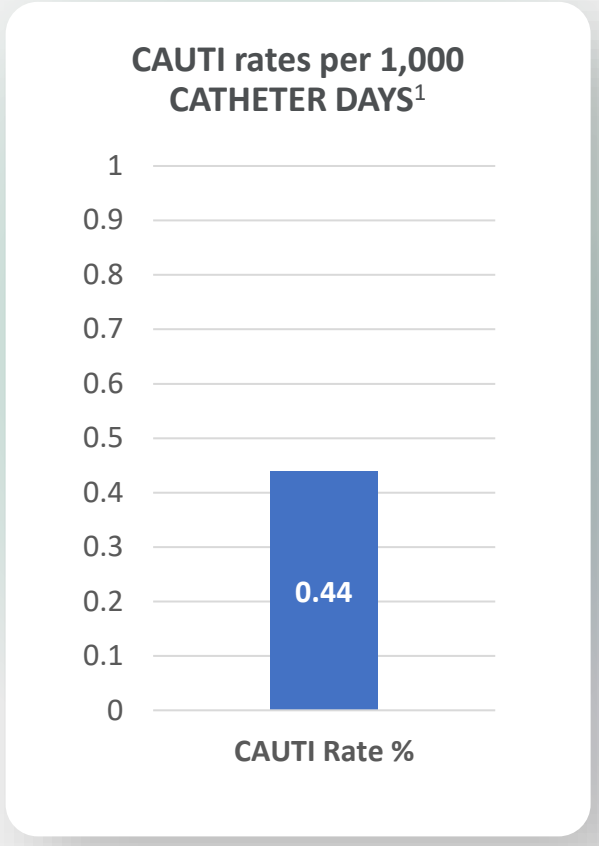
$6.2B
Spent in healthcare due to CAUTIs in the USA

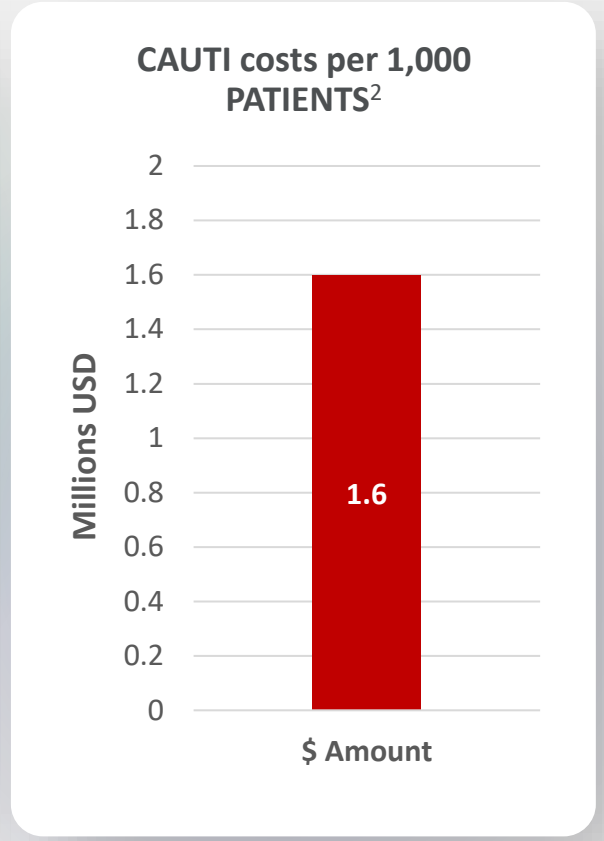
1. National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure. https://www.hospitalsafetygrade.org/media/file/CAUTI.pdf accessed August 15, 2020
2. Catheter-associated urinary tract infection. The Institute for Healthcare Improvement. http://www.ihi.org/Topics/CAUTI/Pages/default.aspx 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

Ur24T

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[3]

- 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 CAUTI is Over $6.2 Billion.***[3]

1. (https://www.hospitalsafetygrade.org/media/file/measure_sheet_CAUTI.pdf). Based on $13,793 per patient
3. https://www.ahrq.gov/hai/pfp/haccost2017-results.html#cau
4. 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.

30
days in home use

Could be used multiple times
on one patient - after use, wash with Ur24T antibacterial spray or soap and water

15
days hospital use

Ur24T

TrueClr Adult Catheters

F
Female
Catheter

M
Male
Catheter

M+
Male
Catheter

Ur24T

TrueClr Pediatric Catheters

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

IF
Infant Female Catheter

IM
Infant Male Catheter

Ur24T

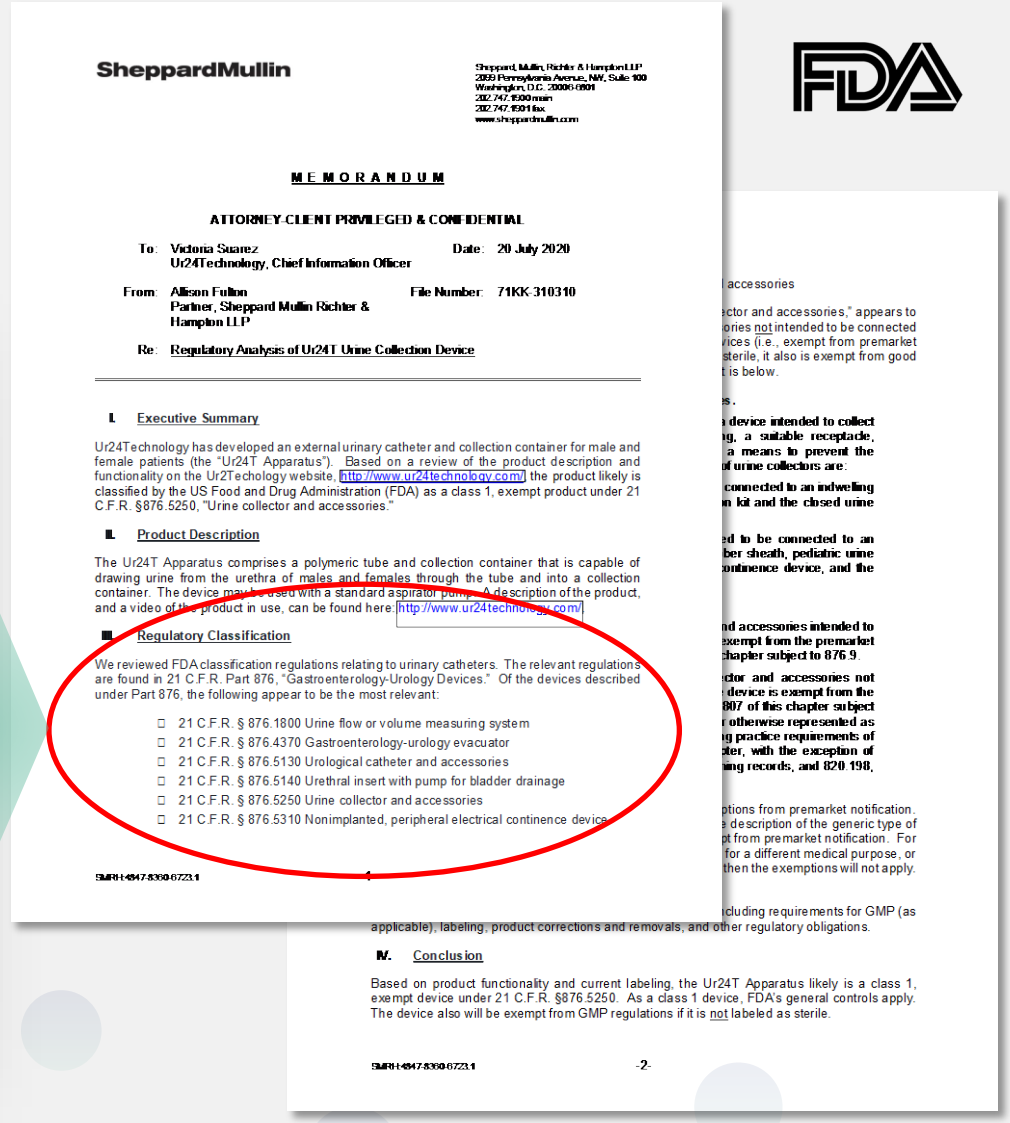
FDA Approval Letter

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

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MEMORANDUM

ATTORNEY-CLIENT PRIVILEGED & CONFIDENTIAL

To: Victoria Suarez
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

Ur24Technology 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 Ur2Techology website, http://www.ur24technology.com/ the product likely is classified by the US Food and Drug Administration (FDA) as a class 1, exempt product under 21 C.F.R. §876.5250, "Urine collector and accessories."

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 may be used with a standard aspirator pump. A description of the product, and a video of the product in use, can be found here: http://www.ur24technology.com/

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:

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- 21 C.F.R. § 876.5310 Nonimplanted, peripheral electrical continence device

SMRH:4847-8360-6723.1

-1-

...accessories

...ector 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.

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

...connected to an indwelling ...n kit and the closed urine

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

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

...ector and accessories not ...device is exempt from the ...807 of this chapter subject ...otherwise represented as ...g practice requirements of ...ster, with the exception of ...ing records, and 820.198.

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

...cluding requirements for GMP (as applicable), labeling, product corrections and removals, and other regulatory obligations.

IV. Conclusion

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.

SMRH:4847-8360-6723.1

-2-

Improving Patient Outcomes by Revolutionizing Care

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

	TrueClr	BD PureWick™	Stryker™ Primofit	Coloplast™ Coveen
Empties the Bladder Automatically	✓	✗	✗	✗
Use In Males	✓	✓	✓	✓
Use in Females	✓	✓	✗	✗
Use in Pediatrics	✓	✗	✗	✗
Portable	✓	✗	✗	✓
Avoids Urine to Skin Contact	✓	✗	✗	✗
Non-Adhesive Application	✓	✓	✗	✗

TrueClr Hospital Utilization

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: Step Down Units

- 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

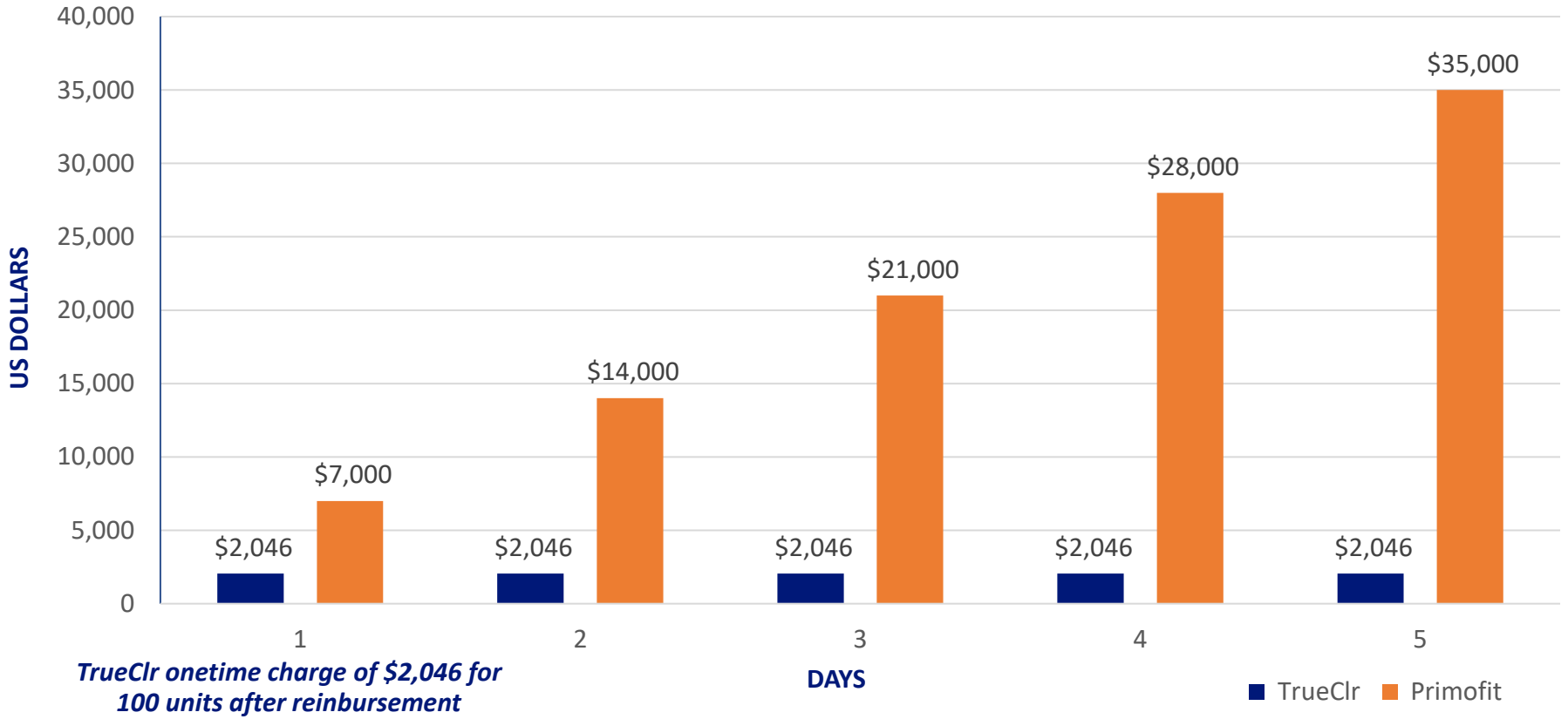
- Outpatient procedures
- Increase efficiency
- Decrease opportunities for Hospital Acquired Infections-CAUTIs
- Improved patient comfort
- Reduced trauma to urethra / bladder

TrueClr: Value Proposition | 100 UCAs vs. Primofit

Ur24T recommends to clean catheter once every 24 hours in hospital • Guarantees 30 days if used at home

TrueClr vs SAGE PRODUCTS Now part of Stryker.

100 /disposable start saving money at **day 1** comparing to Primofit



TrueClr onetime charge of $2,046 for 100 units after reinbursement

$32,954

OVERALL SAVINGS AFTER ONLY

5

DAYS

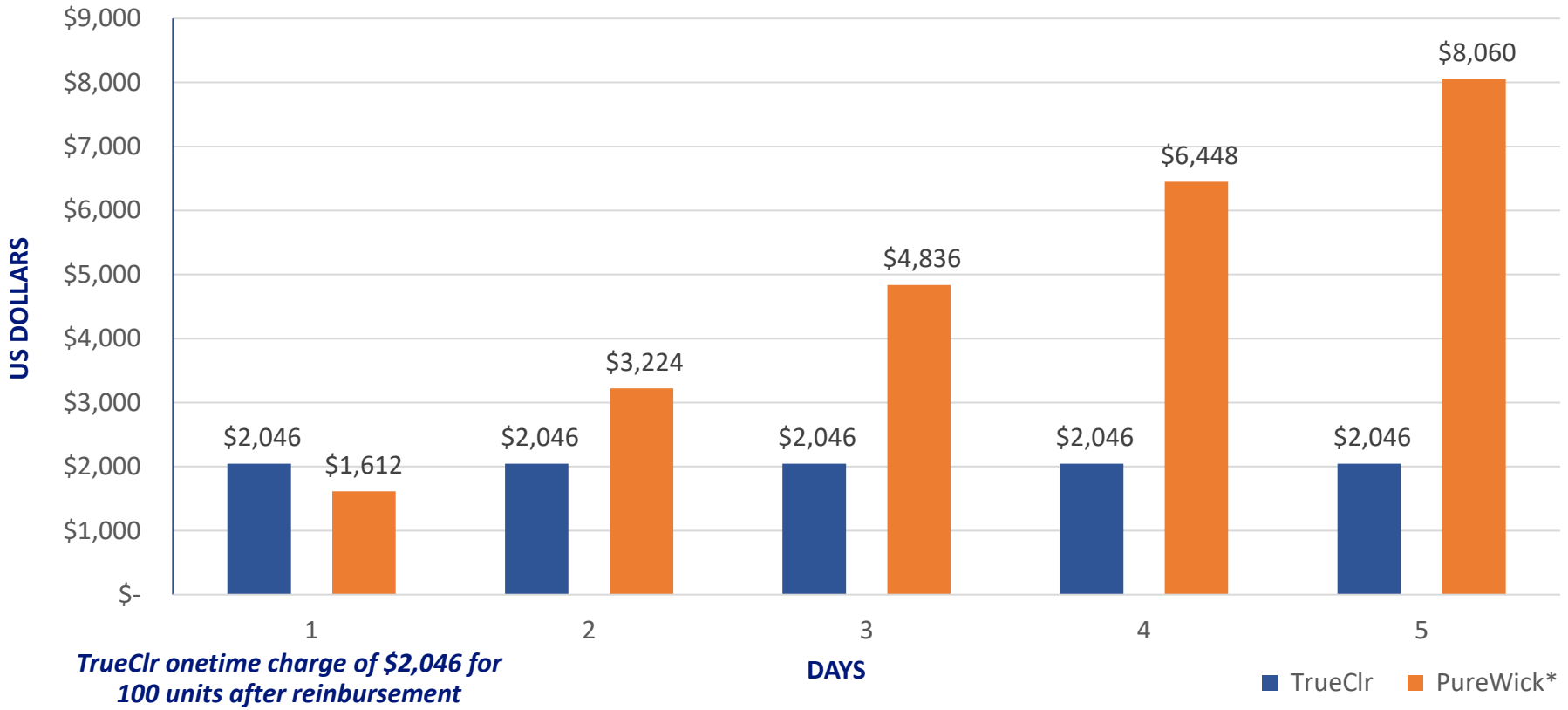
Ur24T

TrueClr: Value Proposition TrueClr vs Purewick

Ur24T recommends to clean catheter once every 24 hours in hospital • Guarantees 30 days if used at home

TrueClr vs **BD**

100 UCAs at $109/disposable start saving money at **day 2** comparing to Purewick



TrueClr onetime charge of $2,046 for 100 units after reinbursement

$6,014

OVERALL SAVINGS AFTER ONLY

5

DAYS

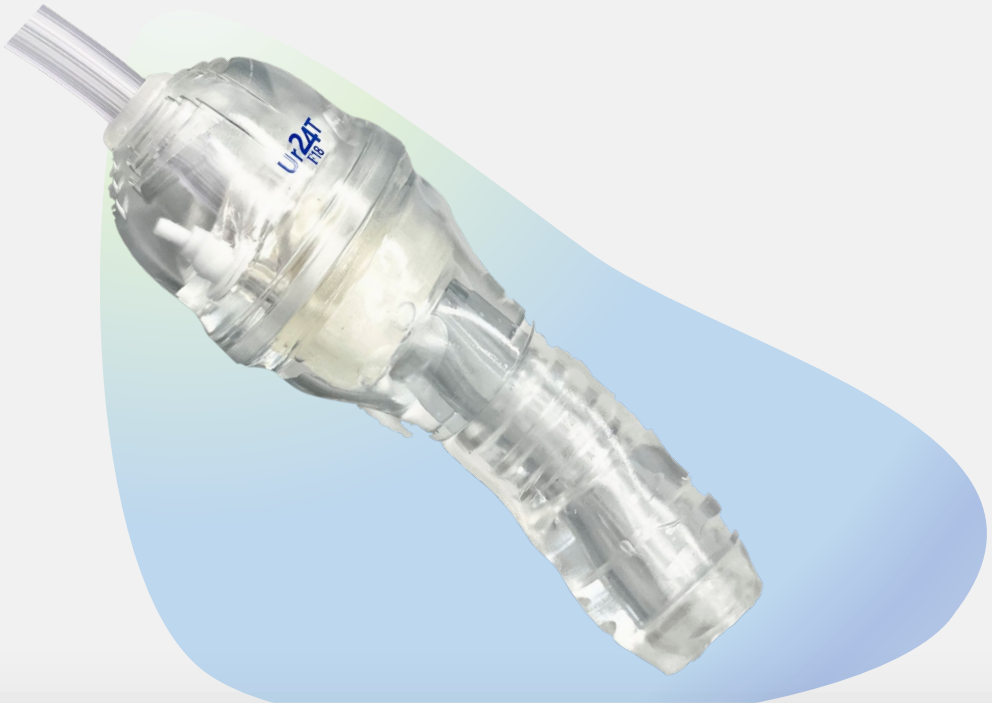
*Assumes PureWick change 2 times per 24 hours.

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

Ur24Technology®

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

Ur24T



Ur24Technology®

THANK YOU!