



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

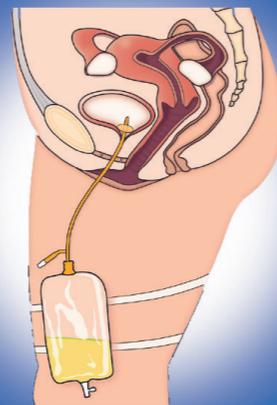
deaths per year from internal catheters

Nearly 1 in 3

acute care hospital infections are caused by CAUTIs¹

80%

of all hospital-acquired urinary tract infections are a result of internal catheters²



~449,334

CAUTI events occur per year in the US¹

#1 risk factor

for developing a CAUTI is prolonged use of a urinary catheter²

Over 2.8 million

antibiotic-resistant infections occur in the US each year³

\$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

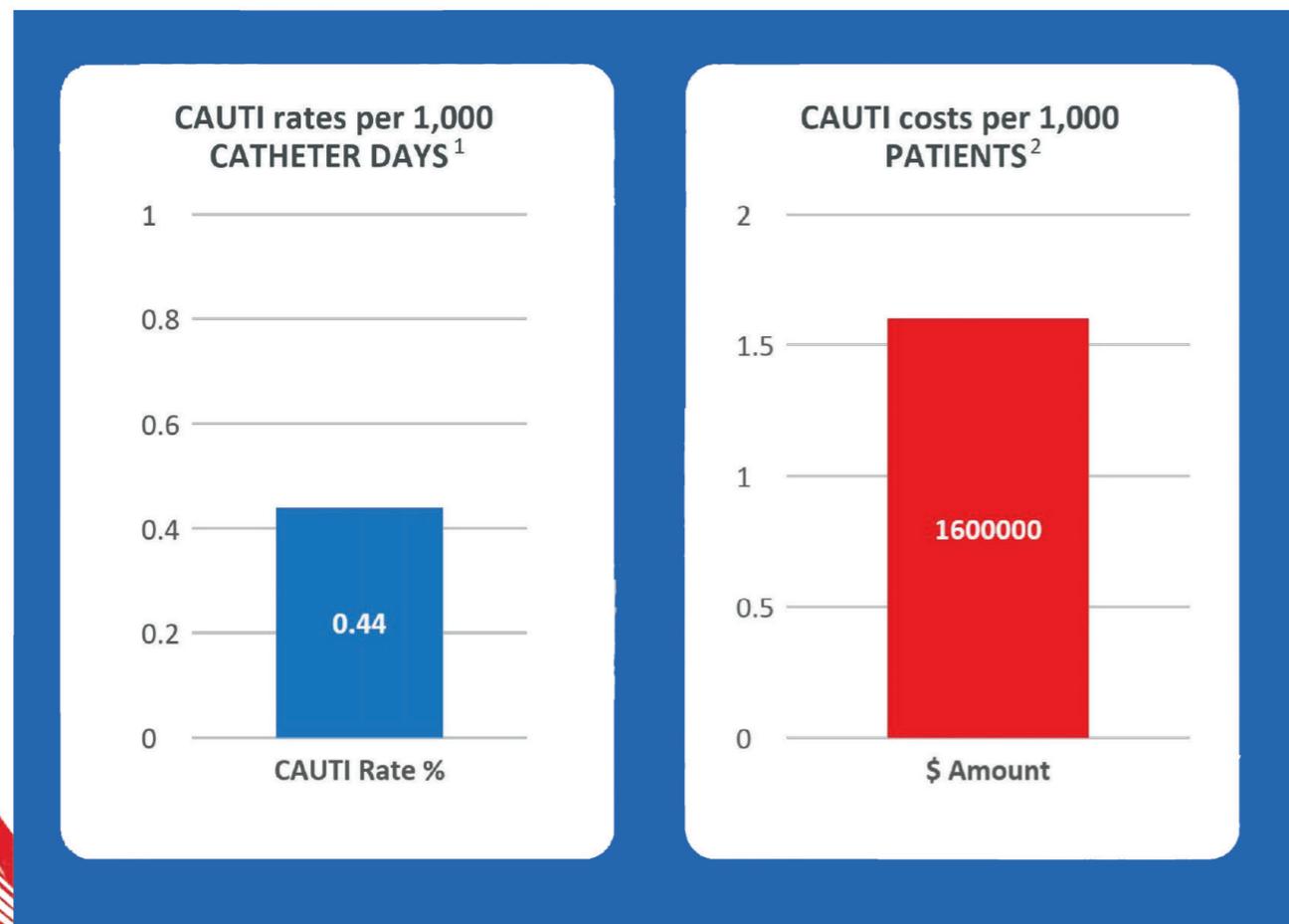
2. Catheter-associated urinary tract infection. The Institute for Healthcare Improvement. <http://www.ihc.org/Topics/CAUTI/Pages/default.aspx> accessed August 15, 2020

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 CAUTIs³



- 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. COST OF CAUTIs³**

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.

30
days use in
home



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

15
days hospital
use

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



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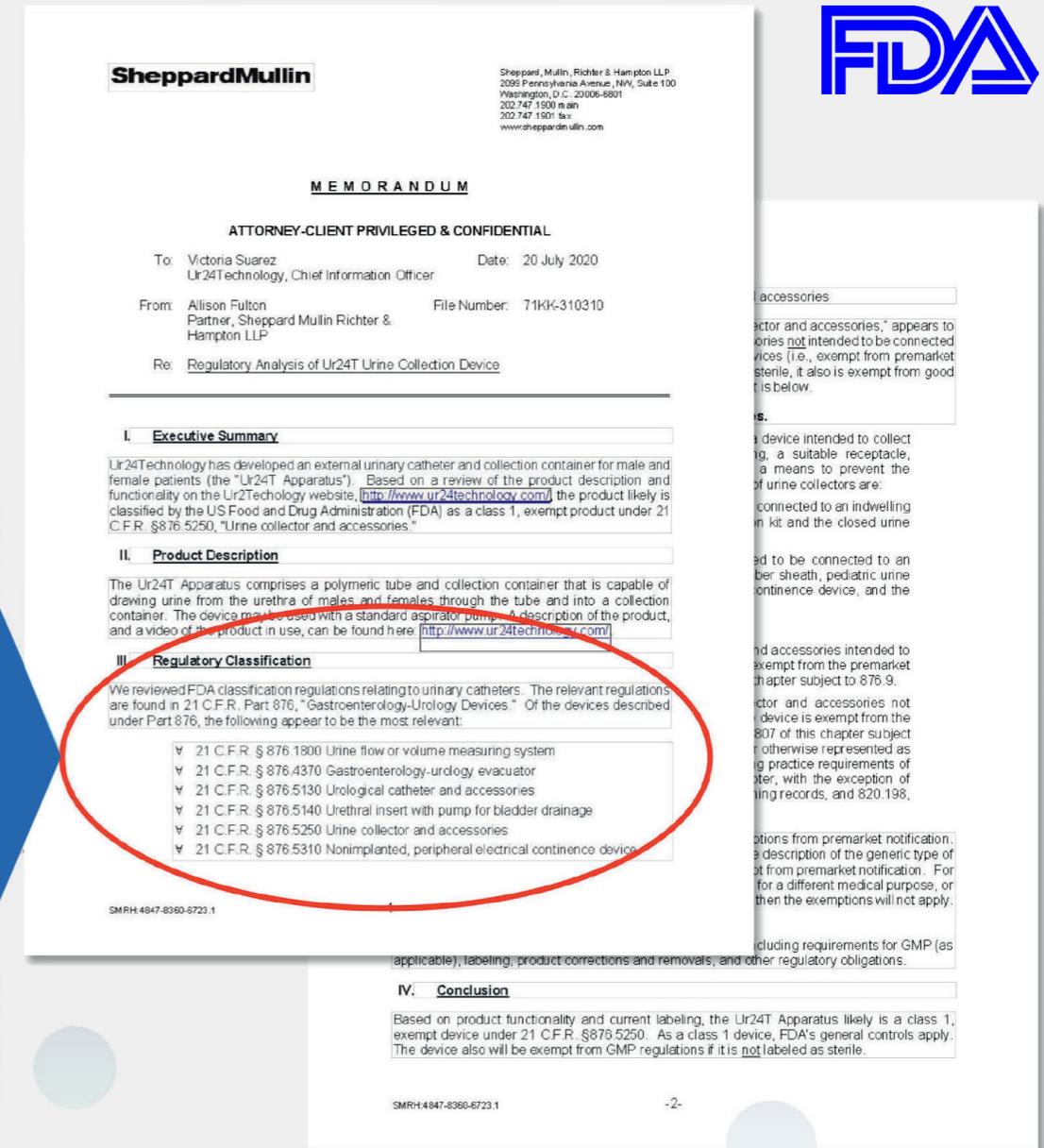
FDA Approval Letter

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



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	✓	✗	✗	✗
Use in Males	✓	✗	✓	✓
Use in Females	✓	✓	✗	✗
Use in Pediatrics	✓	✗	✗	✗
Portable	✓	✗	✗	✓
Avoids Urine to Skin Contact	✓	✗	✗	✗
Non-Adhesive Application	✓	✓	✗	✗

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



TrueClr Hospital Utilization: Intensive Care Units "ICU"

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



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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



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

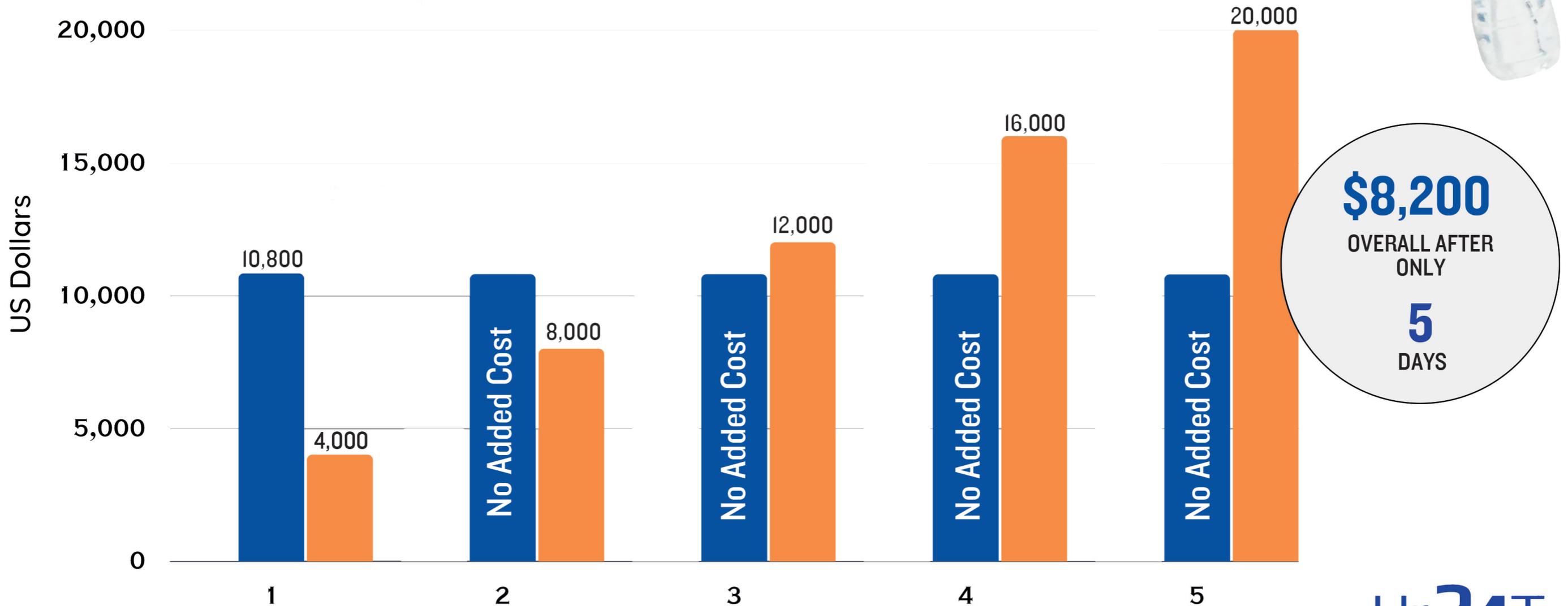
Ur24T recommends to clean catheter once every 48 hours in hospital

- Guarantees 30 days if used at home



TrueClr vs  BD

100 UCAs at \$108/ disposable start saving money at day 3 comparing to Purewick



TrueClr Onetime charge of \$10,800 for 100 units

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

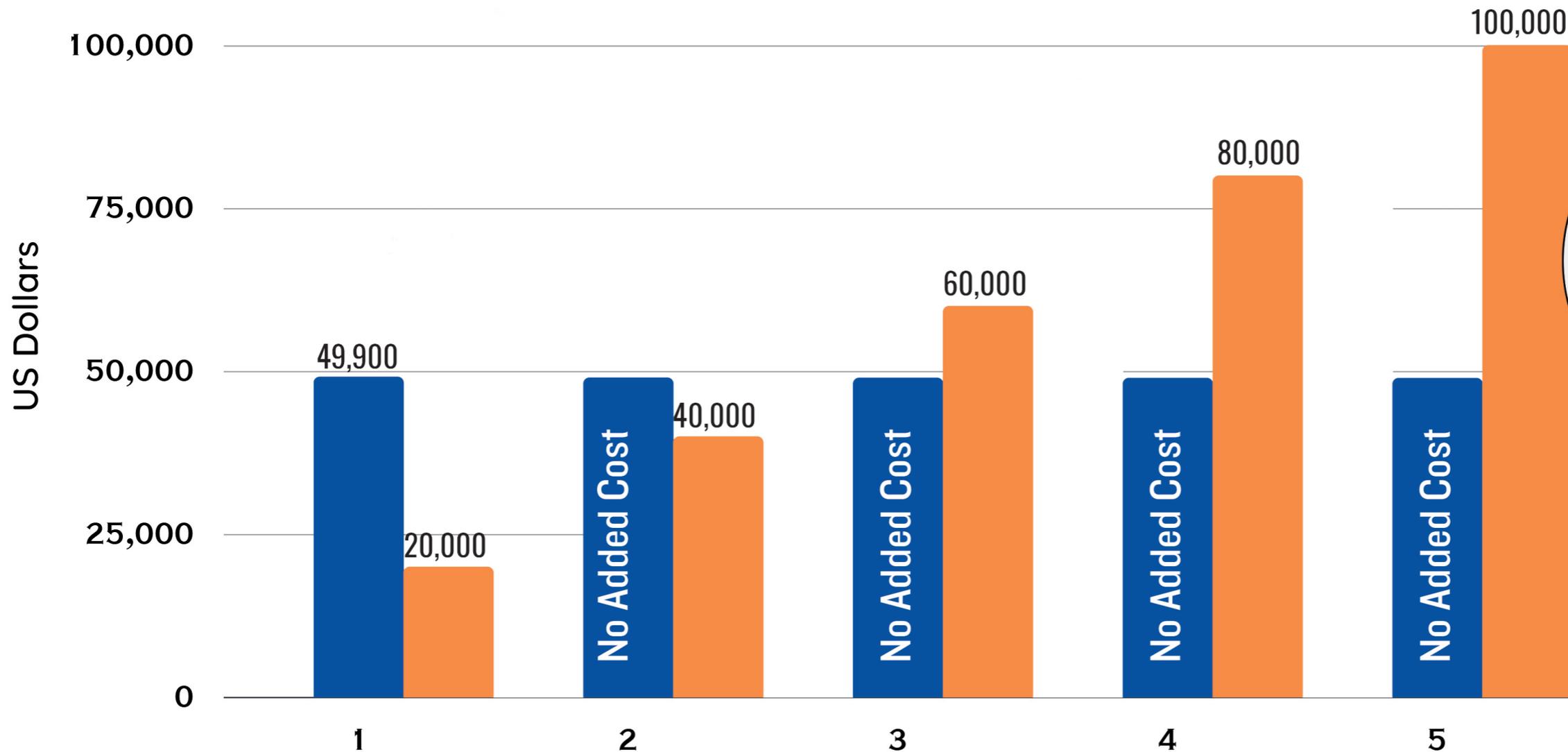
Ur24T recommends to clean catheter once every 48 hours in hospital

- Guarantees 30 days if used at home



TrueClr vs  BD

500 UCAs at \$98/ disposable start saving money at day 3 comparing to Purewick



\$51,000
OVERALL AFTER
ONLY
5
DAYS

TrueClr Onetime charge of \$49,000 for 500 units

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

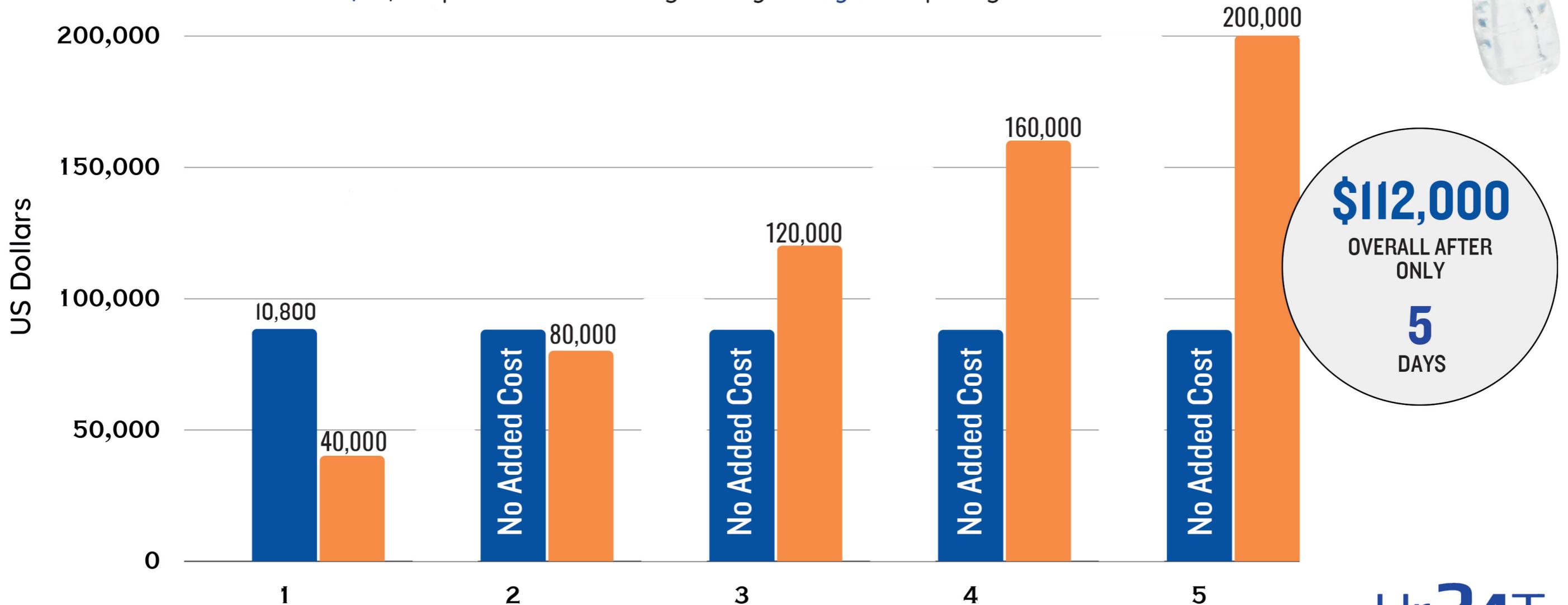
Ur24T recommends to clean catheter once every 48 hours in hospital

- Guarantees 30 days if used at home



TrueClr vs  BD

1000 UCAs at \$88/ disposable start saving money at day 3 comparing to Purewick



TrueClr Onetime charge of \$88,000 for 1000 units

Ur24T



DemeTECH[®]

“A Trusted Name in Medicine”

- **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**

Ur24T

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



thank
you!