

# Cost-Effective Implementation of Closed System Transfer Devices (CSTDs) to Comply with USP General Chapter <800>

## INTRODUCTION

Awareness of the dangers of exposure to hazardous drugs (HDs) used in healthcare has increased dramatically in recent years. As this understanding has evolved, so has industry regulation calling for use of environmental controls to help keep patients and healthcare workers safe. One organization active in the guidance of safe drug handling practices in the United States is the U.S. Pharmacopeial Convention (USP), which maintains a comprehensive set of drug handling standards enforceable by the United States Food and Drug Administration (FDA) and referenced in over 140 countries around the world.<sup>1</sup>

In the most recent update to its comprehensive standards, USP's proposed Chapter <800> (USP <800>) will for the first time require facilities to utilize CSTDs during administration to patients, while encouraging compounding facilities to utilize CSTDs during hazardous drug preparation. While the comprehensive USP <800> safe handling guidelines will have significant budgetary implications for healthcare facilities, implementing CSTDs can be one of the most cost-effective ways to start improving safety and compliance.

Although health system pharmacy leaders recognize the mounting evidence supporting the use of CSTDs, they have struggled to accept the relatively high cost of implementation. As a result, the adoption of CSTDs in US hospitals has grown slowly, reaching only 41% in 2014.<sup>2</sup> Of the hospitals yet to implement, nearly 80% cited cost as a main barrier, pointing to the imminent need for facilities to identify cost-effective solutions to keep them both safe and in compliance with USP <800>.

Of the handful of CSTDs on the market, ICU Medical's ChemoClave<sup>®</sup> and ChemoLock<sup>®</sup> CSTD systems offer a variety of cost-effective USP <800> compliant solutions. One study showed that ChemoClave, in particular, was the most cost-effective CSTD solution for facilities to implement.<sup>3</sup> With availability of both manual and automated CSTD compounding technology, ICU Medical CSTD technology can help facilities cost-effectively adhere to USP <800> guidelines, regardless of preparation volumes and frequencies.

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## Compounding

Using ICU Medical CSTDs for HD compounding can help minimize costs by allowing you to:

1. Implement the lowest cost CSTD
2. Utilize multi-packs and specialty kits for volume-based savings
3. Minimize costs with automated compounding technology

## Administration

Using ICU Medical CSTDs for HD administration can help minimize costs by allowing you to:

1. Avoid replacing administration sets for patients receiving multiple drugs per treatment
2. Avoid additional components required for nursing

## USP CHAPTER <800> SPOTLIGHT ON CSTDS

USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings in the Pharmacopeial Forum (PF) proposes new standards to protect personnel and the environment when handling HDs. These standards highlight the role of CSTDs throughout the HD handling process, from drug compounding in the pharmacy to transportation and administration to patients. This new direction regarding CSTD use is stronger than that found in the preceding Chapter <797>. While the older guidelines state that CSTD use is “preferred” the proposed Chapter <800> guidance states that “CSTDs **should** be used when compounding HDs when the dosage form allows” and that “CSTDs **must** be used when administering HDs when the dosage form allows.”<sup>4</sup>

Section 11 of USP <800> adds that each facility must establish standard operating procedures (SOPs) for the labeling, handling, packaging, and transport of HDs that address the, “prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit.”<sup>4</sup> Among the exposure-reducing strategies listed, USP <800> specifies the use of CSTDs to facilitate safe handling compliance.

### Minimizing Costs of CSTDs Used in the Pharmacy

There are multiple ways in which health system pharmacy leaders can control the cost of implementing CSTDs, but the true financial impact of using the devices is dependent on the volume of daily mixes performed in the pharmacy. For hospitals and cancer centers compounding fewer than 30 HD preparations each day, manual (by hand) CSTD compounding technologies are generally the most cost-effective, while high-volume facilities compounding greater than 30 preparations per day can more effectively offset the cost of CSTDs by implementing automated compounding technologies featuring reusable CSTD components.

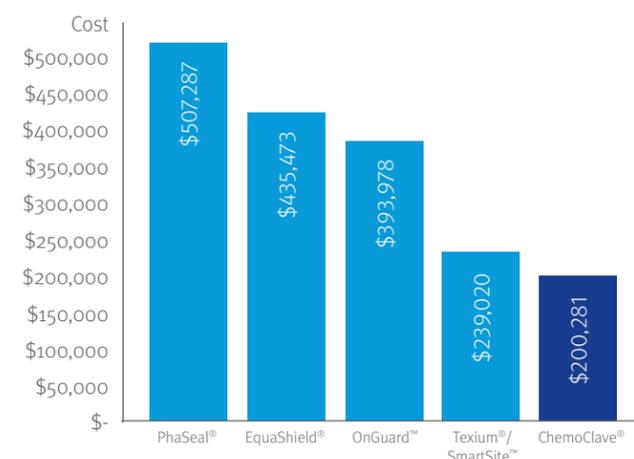
The majority of CSTDs offered by providers including Becton Dickinson and Company (PhaSeal™/Texium®), Equashield, LLC (Equashield®), and B Braun (OnGuard™), are limited to manual compounding solutions. While ICU Medical CSTDs are similarly offered as manual systems, they have also been integrated into the Diana™ automated drug compounding system to enable facilities of all sizes to cost-effectively comply with USP <800> recommendations in the pharmacy.

#### MINIMIZING CSTD COSTS FOR LOW-VOLUME COMPOUNDING FACILITIES

##### 1. Implement the Lowest Cost CTSD

Low-volume pharmacies rely on manual CSTD compounding methods that require single-use CSTD components for each preparation. As a result, the first determinant of CSTD affordability for these facilities is the cost of the devices themselves. A comparison of total annual costs associated with implementing the various CSTDs is illustrated in Figure 1. Component costs may vary slightly due to manufacturing price changes, contract pricing, and/or volume discount pricing, but in most cases, the ChemoClave System, which meets the definition of a closed system, is the lowest cost option for standalone CSTD components in the marketplace today.

FIGURE 1: TOTAL ANNUAL COSTS ASSOCIATED WITH IMPLEMENTING COMPETING CSTDS<sup>3</sup>



Component cost may vary slightly due to manufacturing price changes, contract pricing, and/or volume discount pricing. Texium/SmartSite is marketed as a closed system, not a CSTD.

In some cases, the volume of drug required for an IV push is actually greater than the volume of a single syringe, requiring technicians to use as many as five syringes for a single treatment, each with a disposable CSTD syringe component. In instances where multiple syringes and vial adapters are used for a single preparation, the savings achieved by using lower-cost ChemoClave components will have an even greater impact.

#### MINIMIZING CSTD COSTS FOR HIGH-VOLUME FACILITIES

##### 2. Utilize Multi-Packs and Specialty Kits for Volume-Based Savings

Facilities compounding high-volumes of HD each day are especially vulnerable to the costs associated with high supply usage; however, high volume pharmacies can help offset the costs of CSTD implementation by ordering commonly used items in multi-packs and kits. ChemoClave and ChemoLock CSTD multi-packs provide pharmacies with price discounts on frequently used components, including vial spikes and bag spikes. In addition to multi-pack volume discounts, the ChemoClave and ChemoLock systems allow pharmacies to design specialty kits that include all CSTD components needed for a specific, repeated preparation, all at a cost lower than the sum of the individual components if purchased separately.

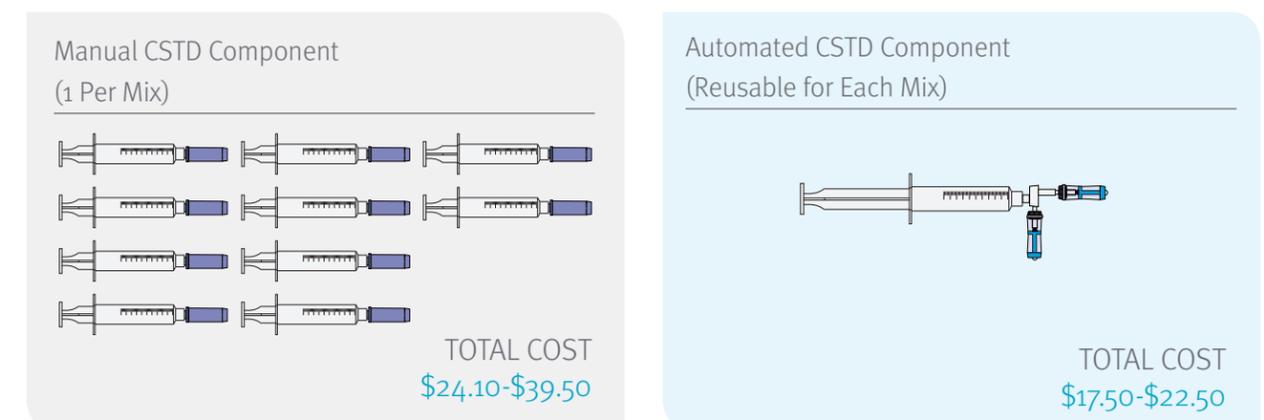
##### 3. Minimize Costs with Automated Compounding Technology

High-volume compounding facilities can also minimize CSTD costs by implementing automated compounding technology that integrates reusable CSTD components. Substituting reusable CSTD components for single-use components helps decrease the cost per mix as volumes of preparations of the same medication increase, eventually bringing costs per mix below that of manual, single-use methods (Figure 2).

Currently, the only available automated drug compounding system that integrates CSTD technology is the Diana automated drug compounding system. The Diana system uses ChemoClave or ChemoLock CSTD components to minimize exposure to HDs and preserve drug sterility, while offering the clinical accuracy and ergonomic benefits of compounding automation.

The ChemoClave System was shown to cost between \$38,739 and \$307,006 less to implement than competing systems.<sup>3</sup>

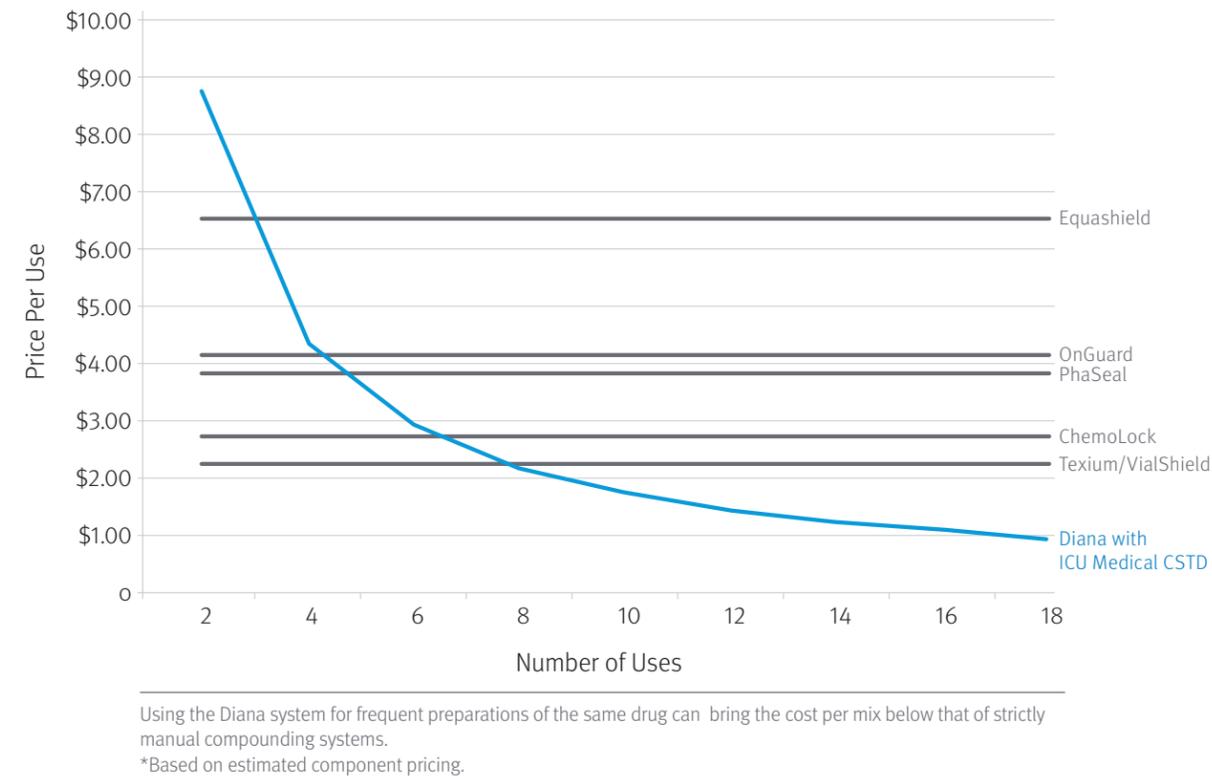
FIGURE 2: MANUAL VS. AUTOMATED COMPOUNDING: CONSUMABLE ANALYSIS USING AN EXAMPLE OF 10 PACLITAXEL 60CC MIXES PER DAY



The Diana system integrates a reusable CSTD component that transfers HD from a vial into a patient IV bag or syringe. As a result, this reusable component replaces the need for single-use syringe adapters that would normally be disposed of after each use, allowing the cost per mix of CSTD disposables to decrease the more times the system is used (Figure 3).

With options for acquiring the Diana system at no up-front capital cost, high-volume compounding facilities can comply with USP <800> CSTD recommendations more cost-effectively than with strictly manual CSTD solutions, while gaining the added benefits of compounding automation.

FIGURE 3: ECONOMY OF SCALE USING THE DIANA AUTOMATED COMPOUNDING SYSTEM WITH ICU MEDICAL CSTDs\*



### Additional Benefits of Automated Compounding with the Diana System

In addition to helping minimize CSTD costs for high-volume compounding facilities, the Diana system can help efforts to improve the accuracy, safety, and efficiency of hazardous drug preparation.



User-Controlled Automated Compounding for Maximum Accuracy and Safety



Increases Efficiencies by Allowing for Multitasking



Reduces Risk of Repetitive Stress Injuries



Closed System Ensures Safety of Clinicians and the Sterility of the Mix

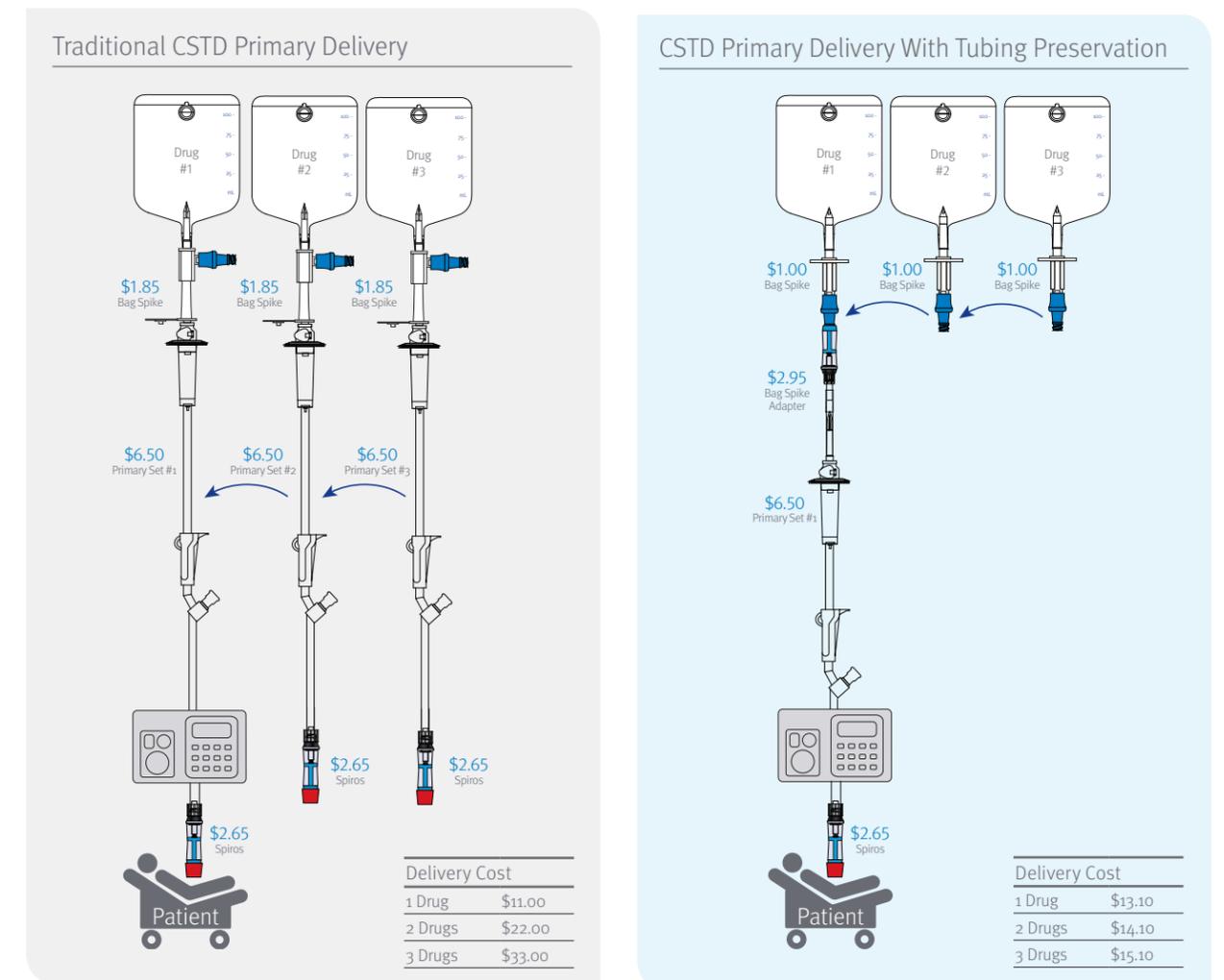
### Minimizing Costs of CSTDs Used in Nursing

USP <800> CSTD language is strongest in its guidance for CSTD use during patient administration. This new guidance mandates the use of CSTDs for the safe administration of HDs, stating “CSTDs must be used when administering HDs when the dosage form allows.” CSTDs used during the administration process take the form of bag spikes, administration sets, and other components that help maintain closed systems during both IV pump infusion and direct IV push delivery. Mandating the use of these safe handling systems during administration will undoubtedly help improve nursing safety by minimizing the risk of dangerous exposure to HDs, but the added expense may also have a significant budgetary impact. As a result, potential areas for added cost savings must be carefully analyzed before selecting and implementing a new CSTD for HD administration.

#### 1. Avoid Replacing Administration Sets for Patients Receiving Multiple Drugs Per Treatment

Traditionally, when patients receive additional HDs during a single treatment, the previous drug bag is discarded along with the entire administration set. As a result, each additional drug delivery requires a new primary or secondary set along with the new drug bag. The ChemoClave and ChemoLock systems incorporate unique CSTD adapter technology to eliminate the need to replace primary pump set or secondary set tubing (Figure 4) for patients receiving multiple drug

FIGURE 4: PRODUCT COMPARISON FOR PATIENTS RECEIVING THREE DRUGS PER TREATMENT VIA PRIMARY SET



ICU Medical's CSTD systems offers multiple cost-savings strategies that are unique to the system and may not be achievable with other systems.

By minimizing CSTD components and administration tubing required for patients receiving multiple drugs per chemotherapy treatment, facilities may experience substantial cost savings, outlined in the model in Table 1. This scenario highlights the potential cost savings using ICU Medical CSTD tubing preservation components for a range of facilities preparing different volumes of hazardous drugs per year. In this example, a large health system preparing 60,000 mixes per year may potentially save up to \$264,000 per year by utilizing tubing preservation strategies.

TABLE 1: Potential Cost Savings Using CSTD Tubing Preservation (Primary Set Delivery)\*

Preps Per Year	1 Drug (50%)	2 Drugs (35%)	3 Drugs (15%)	Savings Per Year
5,000	2,500	1,750	750	\$22,000
20,000	10,000	7,000	3,000	\$88,000
60,000	30,000	21,000	9,000	\$264,000

\*Based on an estimated distribution of 50%, 35%, and 15% of patients receiving 1, 2, and 3 drugs per treatment, respectively.

## 2. Avoid Additional Components Required for Administration

CSTD systems with non-ISO standard luer connections may require the use of extra components or adapters in order to access ISO-standard luers on a patient's IV line. These additional components increase costs and complexity for the nursing staff. In contrast, ICU Medical's luer-based ChemoClave system can be connected to any needlefree connector, helping minimize costs by eliminating the need for any extra components during administration.

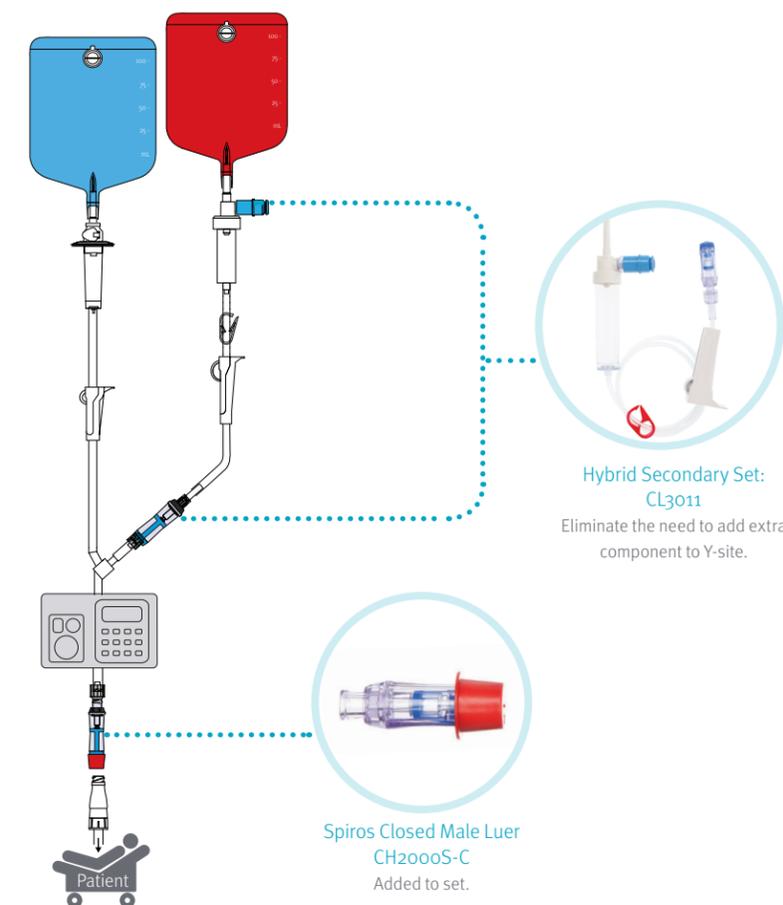


ChemoClave, which includes the Spiros® closed male luer, uses intuitive, luer-based technology to help you cost-effectively minimize exposure to hazardous drugs and comply with recommended guidelines.

therapies. For each primary and secondary set scenario, CSTD bag spikes can be safely disconnected from the closed male luer on the primary set adapter or ICU Medical secondary set. As a result, primary and secondary administration tubing can stay in place for a patient receiving multiple drug therapies in a single treatment, helping to minimize treatment costs and maximize workflow efficiencies.

In some situations, a facility may implement both the ICU Medical ChemoLock system and Spiros closed male luer if pharmacists and technicians prefer the single-motion, click-to-lock design of the ChemoLock system, but oncology nurses prefer the intuitive, luer-based design of the Spiros for administration to patients. In order for Pharmacy and Nursing to use both preferred CSTD technologies for a single patient preparation, ICU Medical developed a variety of "hybrid" administration sets that combine ChemoLock's proprietary locking technology with the Spiros luer-based component on the administration or patient end of the set (Figure 5). This form of hybrid CSTD administration set can help facilities safely and efficiently comply with USP <800> guidelines while implementing cost-effective, user-preferred technologies that require no additional components for administration.

FIGURE 5: ICU MEDICAL HYBRID ADMINISTRATION EXAMPLE



The sample set above uses ChemoLock CSTD technology on the bag spike port for easy pharmacy preparation while incorporating ChemoClave (Spiros) luer-based technology on the patient end for safe and easy administration.

## CONCLUSION

ICU Medical's ChemoClave and ChemoLock systems offer the most comprehensive and cost-effective CSTD solutions for facilities of all sizes and compounding volumes. These CSTD systems also allow high-volume compounding pharmacies to experience the benefits of compounding automation while minimizing overall CSTD costs. With unique components that allow for the preservation of administration tubing, ICU Medical CSTDs may help large health systems save up to an additional \$264,000 per year by minimizing the tubing and components required for patients receiving multiple chemotherapy drugs per treatment. Ultimately, minimizing CSTD implementation costs with ICU Medical's proven CSTD solutions can make it easier for healthcare workers at hospital pharmacies and cancer centers to comply with USP <800> safe handling guidelines while working to improve the health and wellbeing of patients fighting through some of the most challenging times of their lives.

## References

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3. Barnachea L, Lee T, Gitler J, Saria M. Cost Determination Study of Closed System Transfer Devices (CSTD). Presented at the California Society of Health System Pharmacists (CSHP), November 4, 2011.
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