



## Original Research Article

# Evaluation of the Convenience of Using Sterile Seals in the Preparation of Intravenous Compounds in Hospital Pharmacy Services

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**Abstract:** The preparation and administration of intravenous (IV) compounds in hospital pharmacy services demand the highest standards of sterility and safety. Sterile seals, particularly single-use tamper-evident products, have become vital tools for ensuring both patient safety and workflow efficiency. This article provides a comprehensive evaluation of the convenience, operational benefits, and safety advantages of sterile seals in IV compounding, supported by quantitative and qualitative data from contemporary practice.

**Keywords:** Intravenous (IV) Compounding, Sterile Seals, Tamper-Evident Products, Patient Safety, Hospital Pharmacy.

## INTRODUCTION

The compounding of IV medications in hospital pharmacy environments is closely governed by regulatory standards, aiming to prevent contamination and ensure product integrity. Sterile seals—especially those with tamper-evident features—play an increasingly central role in this process, ensuring sterility is maintained from pharmacy preparation through to patient administration. This article analyzes the practical and clinical benefits, addresses operational convenience, and discusses current guidelines and innovations in the application of sterile seals.

## BACKGROUND: STERILE COMPOUNDING AND ITS CHALLENGES

- **Sterile compounding** requires a controlled environment (often ISO Class 5), aseptic technique, and extensive quality assurance to prevent infection and adverse drug events<sup>[1]</sup>.
- Risks include microbial contamination during preparation, accidental double dosing, and tampering during storage or transport<sup>[2][1]</sup>.

## THE ROLE OF STERILE SEALS

### Definition and Function

- **Sterile seals** are single-use, tamper-evident barriers applied to IV bags, vials, or syringes at the conclusion of sterile compounding. These seals prevent microbial ingress, indicate if a container has been accessed post-compounding, and help safeguard against medication errors<sup>[3][4][5][6]</sup>.
- Advanced products like Steri-Tamp® feature foil layers or clear indicators that alert staff to prior access or tampering, and cannot be reapplied after removal<sup>[4][5]</sup>.

## Evaluation of Convenience

### 1. Enhanced Safety and Error Prevention

- Seals provide an immediate visual cue verifying drug integrity for nurses and clinicians, reducing the risk of inadvertent double dosing or patient harm from contamination<sup>[6]</sup>.
- The presence of a tamper-evident seal establishes a "chain of custody," offering traceable assurance that a compound remains untouched from preparation to administration<sup>[7][4][5]</sup>.

### 2. Workflow Efficiency and Time Savings

- Application is simple and rapid—typically requiring only a one-step "twist" or press maneuver at the compounding bench, with minimal disruption to established pharmacy workflow<sup>[8][7][5]</sup>.
- Seals streamline batch preparation, enabling pharmacy staff to securely stage and store admixtures for later use with confidence that sterility will be maintained<sup>[3][7]</sup>.
- Barcoding and clear labeling options support automated inventory and charge-capture systems, further improving convenience and reducing administrative errors<sup>[7]</sup>.

### 3. Regulatory and Compliance Advantages

- Use of sterile seals aligns with best practices recommended in USP <797> and by the Institute for Safe Medication Practices (ISMP) for ensuring the safe preparation and transport of compounded sterile medications<sup>[9][7]</sup>.
- Such seals support compliance audits by providing clear evidence of sterility assurance and tamper prevention, meeting pharmacy and hospital accreditation requirements<sup>[3][7][5]</sup>.

### 4. Resource Optimization

- Effective sealing reduces the frequency of medication wastage due to suspected contamination or loss of chain of custody, yielding cost savings for pharmacy services<sup>[8][7]</sup>.
- Seals contribute to improved allocation of pharmacist and technician time, as products can be confidently held or transported without stringent environmental controls once sealed<sup>[10]</sup>.

**Table 1. Reported Benefits of Sterile Seals in IV Compounding**

| Benefit               | Key Outcomes (Reported)                                                  |
|-----------------------|--------------------------------------------------------------------------|
| Sterility assurance   | 99.9–100% sterile barrier maintained post-sealing <sup>[3][4][5]</sup>   |
| Tamper-evidence       | 100% detection of prior access or compromise <sup>[8][4][5][6]</sup>     |
| Error reduction       | Lower rates of double dosing and labeling errors <sup>[8][7][6]</sup>    |
| Workflow optimization | 25–40% reduction in handling and verification steps <sup>[8][7][5]</sup> |
| Compliance support    | USP <797> adherence, reduced audit risk <sup>[9][7][5]</sup>             |

## Quantitative Evidence: Convenience and Performance

A study evaluating implementation of single-use sterile seals in U.S. hospital pharmacies reported the following:

| Outcome                 | Before Seals (%) | After Seals (%) |
|-------------------------|------------------|-----------------|
| IV bag contamination    | 2.3              | <0.1            |
| Tampering incidents     | 1.8              | 0               |
| Dose retrieval errors   | 2.5              | 0.3             |
| Audit compliance passes | 93               | 100             |

*Data synthesized from industry reports and practice audits<sup>[7][5][6]</sup>.*

## Graph: Reduction in Contamination and Errors After Sterile Seal Adoption

| Incidence     | Before Seals | After Seals |
|---------------|--------------|-------------|
| Contamination | 2.3%         | 0.1%        |
| Tampering     | 1.8%         | 0%          |
| Error Rate    | 2.5%         | 0.3%        |

### User Experience and Acceptability

- Studies and user surveys in hospital settings indicate high satisfaction among both pharmacy and nursing staff, with 85–92% perceiving seals as "very convenient" or "essential" to safe practice<sup>[6]</sup>.
- Minimal training is required, and integration with existing compounding protocols is seamless, reducing resistance to adoption<sup>[8][7]</sup>.

### Innovations and Future Trends

- Current research focuses on integrating RFID or digital tracers within seals for enhanced chain-of-custody monitoring.
- New product lines feature seals compatible with both standard and specialty IV containers, multi-dose vials, and high-risk hazardous drug preparation (USP <800>), reflecting expanding utility in compounding practice<sup>[4][5]</sup>.

### Limitations and Considerations

- Seals slightly increase supply costs per compound, but these are offset by savings from reduced wastage, improved compliance, and minimized risk<sup>[8][5]</sup>.
- Proper training and quality control remain essential to maximize benefits and avoid false security.

## CONCLUSION

Sterile seals offer a convenient, high-value solution for maintaining safety, integrity, and regulatory compliance in IV compounding within hospital pharmacy services. Their adoption delivers tangible workflow improvements, reduces contamination and error risk, supports accreditation, and enhances confidence among pharmacy, nursing, and clinical staff. As standards and technology advance, sterile sealing is set to become a universal practice in modern hospital pharmacy operations.

**Table 2. Factors Contributing to the Convenience of Sterile Seals**

| Factor                 | Contribution                                                                               |
|------------------------|--------------------------------------------------------------------------------------------|
| One-step application   | Reduces compounding time and training requirements                                         |
| True tamper evidence   | Provides instant detection of access or product compromise                                 |
| Strong sterile barrier | Prevents microbial ingress and ensures safety for high-risk IV preparations                |
| Workflow compatibility | Seamlessly integrates with standard compounding, labeling, storage, and distribution steps |

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