

White Paper: Single-Use Musculoskeletal Injection Kits:

A Standard Procedure to Reduce Secondary Infection

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Message: A single-use injection kit (SUIK) for use as a single injection is the primary solution that complements the CDC and CMS recommended protocols for reducing the risk of secondary infection following musculoskeletal injections.

Keywords:

- Single-dose vial (SDV)
- Multi-dose vial (MDV)
- Musculoskeletal (MSK)
- Single-use injection kit (SUIK)
- Enovachem Manufacturing

Introduction: In recent media coverage and legal proceedings, inappropriate uses of single-dose vial (SDV) and multi-dose vial (MDV) injectable medications have been widely reported. This well-documented aberrant behavior has been present in both inpatient and outpatient settings, with pain management and orthopaedic clinics bearing a high percentage of reported cases. Susceptible pain management procedures may include injecting medications in sterile spaces including the spine, peripheral joints, tendons and tunnels.¹

A single-dose medication vial that is typically preservative-free should not be used for more than one injection. The “One & Only Campaign” by the CDC and Safe Injection Practices Coalition states, “one needle, one syringe, only one time”.² The mishandling of injectable medical products is a multifaceted problem. Inappropriate use and handling of needles, syringes and medications have been reported in CDC and Health Department led outbreak investigations since 1999. Cases have included the same syringe being used for more than one patient, a used syringe penetrating a medication vial, and the contaminated vial subsequently used for another patient.³ Moreover, vials are being left in potentially contaminated areas, there is an improper or lack of standard operating procedures, and multiple health personnel have been reported utilizing MDVs.

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Based on a 2014 report, there have been at least 49 outbreaks reported by the CDC due to “improper use of injectable medicines” since 2001. The outbreaks, which involve transmission of Hepatitis (B,C) and bacterial infections (e.g. Staphy-lococcus), have caused more than 150,000 patients to be tested due to increased risks for secondary infections.¹ Patients acquiring such infections have been hospitalized anywhere from 3 to 41 days.⁴ The potential associated cost of second-ary infections may include, but is not limited to, the cost related to emergency department admission, in-patient hospital stay, possible surgery, post-hospitalization rehabilitation and residual disability.

According to a 2012 CDC statement, “Medications come in very large vials, but they’re often only approved for use in one person. Healthcare providers see that as waste. There’s a desire to use what you’ve paid for. And they don’t understand that they’re putting their patients at risk”.² This need for healthcare providers to use what has been paid for, or be properly reimbursed for what is used, is jeopardizing the health and safety of patients.

A 2014 survey of 5,446 healthcare practitioners revealed that 6% (326) admitted to “sometimes or always” using SDVs for multiple patients. In the same survey, 15% (816) reported using the same syringe to re-enter a MDV “numerous times” for the same patient.³

Unfortunately, these incorrect injection habits appear to be forming early on in the careers of healthcare practitioners. In 2013, a survey was done on 325 student registered nurse anesthetists with at least 3 months of clinical experience. According to the survey results, 4% (14) administered medications from the same syringe to multiple patients, 18% (59) reused needles on the same patient, and 82% (266) reported re-filling used syringes. Moreover, 22% (71) re-used a syringe or needle to withdraw medication from a MDV, and 49% (160) re-entered a SDV to prepare doses for multiple patients.⁵

Solution: What can and is being done about these improprieties?

In an effort to mitigate this issue, the CDC and Centers for Medicare and Medicaid Services (CMS) have outlined and recommended “safe injection practices to prevent transmission of infections to patients”.^{6,7,8} However, a standard protocol in and of itself is not enough to tackle this widespread public health problem.

The use of pre-packaged, single-use, disposable FDA compliant injection kits can be a potential vehicle to complement CDC and CMS injection protocols and actively reduce the risk of secondary infections. Spinal epidural and peripheral nerve block kits are already being manufactured and available for use.⁹ However, such kits do not address the infection issues associated with single-use medications. In an effort to make standard injection kits more widely available, **Enovachem** has created single-use injection kits (SUIKs) with the appropriate dosage designated for musculoskeletal injections.

Enovachem Manufacturing is an FDA registered pharmaceutical manufacturing facility, serving physicians, pharmacies, manufacturers, wholesalers, and distributors. They are cGMP and CFR Compliant, FDA and DEA Registered Manufacturer, and State Board of Pharmacy Wholesaler Licensed. **Enovachem** is licensed as a manufacturer in 85% of the USA, with final applications pending. **Enovachem Manufacturing** specializes in large variety of FDA Convenience Kits used for increased compliance and decreased contamination for in-office procedures, administration, and dispensation. Each product goes through extensive review, paperwork, and processing, prior to being accepted and approved on the FDA Daily Med, Medi-span, Redbook, and First Data Bank pharmaceutical review committees. **Enovachem** products include single-use musculoskeletal injections kits for injecting the tissues commonly treated in an outpatient clinic including peripheral joints (small, intermediate and large), tendons including trigger points, as well as tunnels (carpal, cubital, tarsal, etc.).¹⁰

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Pre-packaged FDA compliant injection kits reduce the potential for human error and environmental contamination. Single-use disposable kits also eliminate the possibility of vial, syringe and needle re-use for more than one patient. These pre-packaged single-use kits are capable of standardizing injection procedures and re-enforcing CDC and CMS injection protocols; therefore, improving patient health and safety by reducing the risk for secondary infections. Furthermore, pre-packaged kits can save in setup time during clinic hours and standardization of the process can save in training time. **Enovachem's** solution must be accompanied by continued efforts to educate the medical community in safe injection practices. In particular, it is crucial that "a single-dose be utilized in a single patient".¹¹ Enovachem products facilitate this change in human behavior in order to improve patient safety by reducing secondary infection.

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