





Thorne Medical, Inc. DBA AseptiKits, LLC 101 N 700 W North Salt Lake, UT 84054-2736 USA Email: sales@aseptikits.com Phone: 844-863-5170

# Intended Use

SyriKit Syringe Sterile Preparation Convenience Kit is intended for the preparation of sterile-filled syringes.

#### Description

SyriKit Syringe Sterile Preparation Convenience Kit includes sterile syringes inside a header bag. The header bag features an integrated 0.22 micron sterilizing-grade filter to sterilize fluids as they enter the kit and syringes. Syringes are capped prior to opening the header bag to maintain sterility.

## **Kit Contents**

- header bag
- integrated 0.22 micron sterilizing-grade filter
- Luer adapters
- sterile syringes
- syringe caps
- cap holder

### Warnings

- 1. Visually inspect the header bag and filter seal.
- 2. Do not use if damaged.
- 3. Do not exceed 75 PSI (5.2 Bar).
- 4. Single-use. Do not reuse.
- 5. Follow institutional protocols for cross-contamination from penicillin and related agents, mutagenic agents, drugs with narrow therapeutic indexes, and high potency drugs.
- 6. Verify filter patency with a bubble test after syringes are filled. Do not use syringes if the filter fails a bubble test.

### Cautions

- 1. Do not use SyriKit Syringe Sterile Preparation Convenience Kit near sharp objects.
- 2. Do not apply excessive force while injecting fluids through the syringe filter.
- 3. Assure that syringe caps are securely affixed after press fitted on each dose syringe.
- 4. Always follow institutional protocols relative to patient and care giver safety.

- 5. Do not attempt to disconnect pre-assembled components except as instructed.
- 6. When compounding multiple solutions, thoroughly mix all solutions before dispensing through the filter and into individual dose syringes to assure concentration integrity.

Patent

Pending

Ð

7. Store preparations in compliance with FDA guidance or USP Chapter 797.

### Instructions for Use

- 1. Unfold the kit onto a flat, clean surface.
- 2. Inspect the header bag and filter seal for damage. Do not use if damaged.
- 3. Draw a volume of drug into an external source syringe and connect it to the filter.
- 4. Prime the filter assembly.
- 5. Move a syringe to the filter location with the cap near the cap holder.
- 6. Insert the cap into the cap holder and remove the cap.
- 7. Connect the syringe to the filter assembly.
- 8. Fill the syringe as prescribed.
- 9. Remove the syringe from the filter assembly and cap.
- 10. Remove the cap and syringe from the cap holder.
- 11. Move the filled syringe away from the filter assembly for ease of use.
- 12. Prepare the next syringe, repeating steps 5 through 11 for each syringe.
- 13. Fill the internal large volume syringe last to store any remaining drug.
- 14. Verify filter patency with a bubble test after syringes are filled. Do not use syringes if the filter fails the bubble test.
- 15. Open the header bag and remove the syringes.
- 16. Label and store the syringes as per institutional protocol.