



Instructions for Use

REF Safety Draw, Pole & Mount 800-0059

REF Safety Draw, Mayo Mount 800-0060

INTENDED USE

Intended use is to maintain sterility while allowing access to non-sterile vials. This protects both patient and staff by helping to prevent dangerous medication mix-up, as well as needle sticks. The intended users of this device are medical professionals within hospitals and surgery centers.

INSTRUCTIONS

Become familiar with patient positioning device's features before use with patient. Always practice use on a nurse, physician or appropriate volunteer prior to using clinically.

HOW IT WORKS

Durable plastic holder accommodates two single-dose and three multi-dose vials at a time. It clamps onto any table surface, mayo stand or intravenous pole. Vials that run out can be replaced with fresh ones at any time during procedure. You'll know vials are secure because they click and lock into place. Vials are held at perfect angle allowing complete emptying, reducing medication waste.

ADDITIONAL BENEFITS

- 1. Patient Protection: Person administering injections can see vial labels at all times, patients receive intended medication and expiration date is visible.*
- 2. Staff Safety: Safety-Draw holds vials, so nurses no longer need to. No more worrying if the doctor's aim isn't great. No more getting stuck with needles. Assistants can stay out of "needle anger zone" at all times.*

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- *Length: 3" +/- 0.5" (8 cm x 1 cm)*
- *Width: 2" +/- 0.5" (5 cm +/- 1 cm)*
- *Depth: 8" +/- 0.5" (20 cm +/- 1 cm) (rail handle extended)*
- *Device Weight: 1.5 +/- 0.5 lbs. (.68 +/- .22 kg)*
- *Single-person installation*
- *Twist Lock/Release Handle*
- *Holds accessory equipment up to 5/8" diameter mounting post*



COMPONENT OVERVIEW

Safety Draw, Intravenous Pole & Mount and Safety Draw, Mayo Pole & Mount maintains sterility while allowing access to non-sterile vials. This protects both patient and staff by helping to prevent dangerous medication mix-up, as well as needle sticks.

GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Product warranty covers product from manufacturing defects for period of 2 years*
- *If damaged in shipping, call Customer Service at (888) 724-8763 or (781) 982-7000 to obtain Return Material Authorization number. For product warranty issues, contact Customer Service.*
- *CE marked medical device according to MDR (EU) 2017/745*
- *Product is maintenance-free, check product condition before next use*
- *Life of device is 5 years under normal use*
- *Store device between -4°F to +86°F (-20°C to 30°C)*

DISPOSAL

- **General** - *Prevent infection by cleaning and disinfecting product before disposal*
- **Packaging** - *Dispose packaging material via household waste according to national requirements*
- *SchureMed accepts back used or retired products - or dispose of product in accordance with national requirements*



PRODUCT USE WARNINGS

WARNING!

Hazards result from incorrect use. Strictly follow Instructions for Use for your Operating Table system.



WARNING! *Do not reuse device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.*

CLEANING RECOMMENDATION

Follow current Association of periOperative Registered Nurses Journal Guidelines for proper cleaning and disinfection procedures.



WARNING!

Adhere to standards for blood-borne pathogens from Occupational Safety and Health Administration. Use recommended protective clothing, gloves, masks and eye protection to clean accessory.

CAUTION

Strictly read/follow manufacturer's directions for cleaning fluids. DO NOT use cleaners containing phenolics.

1. *Remove major contaminants from accessory with disposable materials. Follow appropriate bio-hazard waste disposal procedures.*

2. Apply cleaning fluid liberally to entire accessory and wipe with clean, lint-free cloth until all moisture and cleaning fluid is removed from accessory
3. Let accessory dry

USER NOTICE












Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

UDI Basic UDI-DI: 081001460F0063E8

eIFU Language Versions

To download and print the Instructions for Use, please go to <http://www.schuremed.com/schuremed-eifu>.

Symbol Glossary

Symbol	Title	Symbol Description
	Manufacturer	Indicates the medical device manufacturer.
	Authorized Representative in the European Community	Indicates the authorized representative in the European community.
	Use-by Date	Indicates the date after which the medical device is not to be used.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Medical Device	Indicates the item is a medical device.
	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.



Manufacturer

SchureMed (081001460)

452 Randolph Street, Abington, MA 02351 USA

Toll Free (888) 724-8763 | Ph (781) 982-7000 | Fax (781) 982-7001 | orders@schuremed.com



Authorized Representative

Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands