

Mitosol[®]

(mitomycin for solution)
0.2 mg/vial

Kit for Ophthalmic Use

Read INSTRUCTIONS FOR USE Before Proceeding

Instructions for Use

A. Outer Pack (Figure A)

- One Sterile Chemotherapy Waste Bag
- One Instructions for Use
- One Package Insert
- One Inner Tray
- Two Patient Chart Labels

*The Outer Pack is to be handled, opened, and its **STERILE** contents dispensed by the non-sterile circulating nurse.*

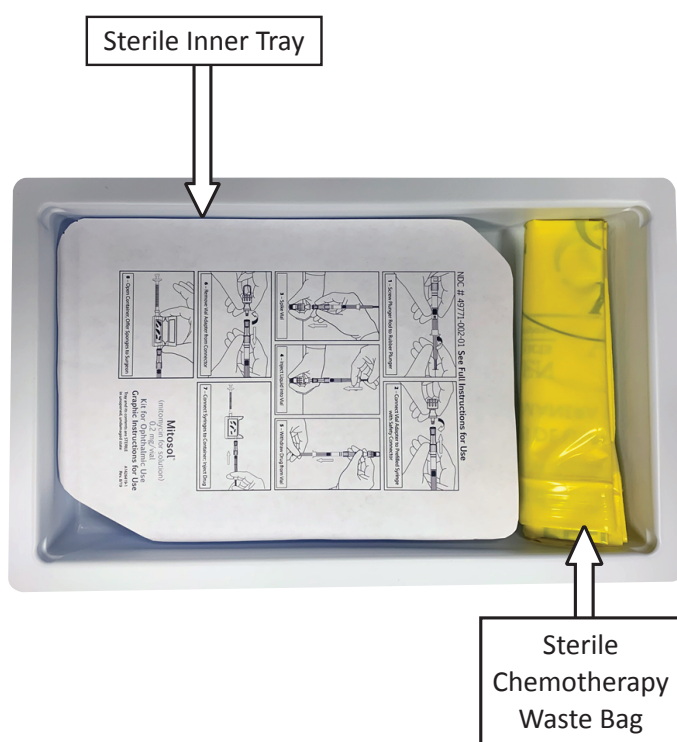


Figure A: Outer Pack

B. **STERILE** Inner Tray (Figure B)

- One Vial Containing 0.2 mg mitomycin (inside protective foam pouch)
- One 1 mL Syringe (Sterile Water for Injection) with Safety Connector
- One Plunger Rod
- One Vial Adaptor with Spike (inside protective foam pouch)
- One 1 mL TB Syringe, Luer Lock
- One Sponge Container Containing:
 - Six 3 mm Absorbent Sponges
 - Six 6 mm Absorbent Sponges
 - Six Half Moon Sponges
 - One Instrument Wedge Sponge
- One Label, MMC (mitomycin)

The Sterile Inner Tray is to be handled, opened, and its contents assembled and dispensed by the sterile scrub technician.

This tray and its contents are **STERILE**.

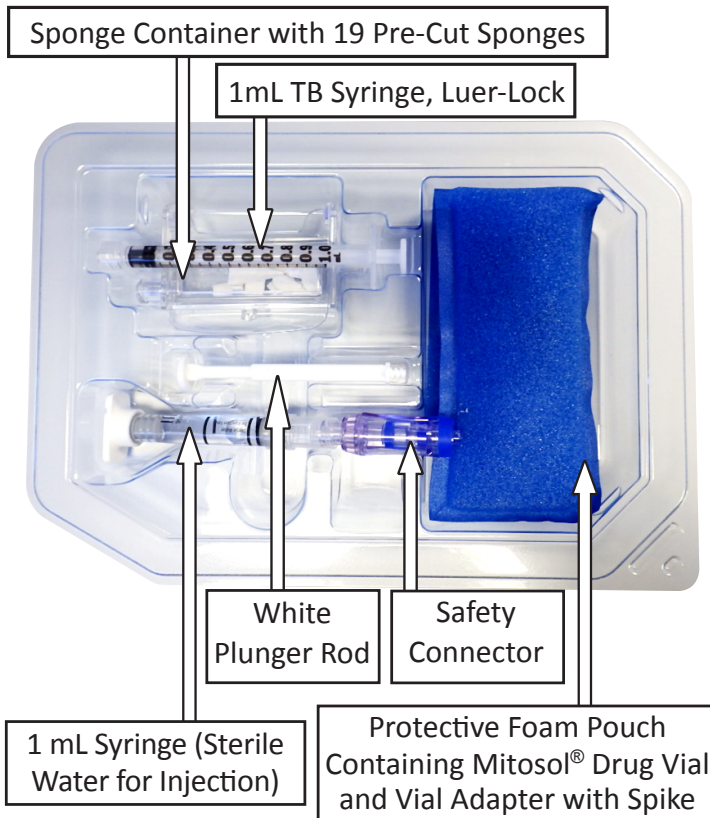


Figure B: Sterile Inner Tray

1. Getting Started

Non-Sterile Circulating Nurse:

Open outer pack. Affect sterile transfer of **ALL** contents to the sterile field.

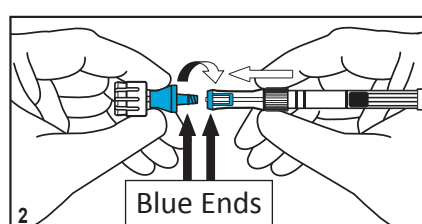
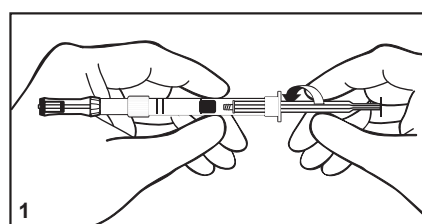
Sterile Surgical Technician:

Open sterile inner tray.

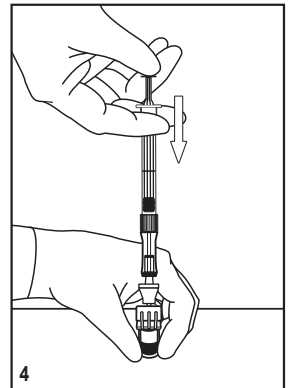
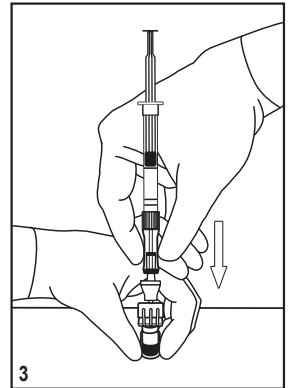
2. Reconstituting Mitosol[®]

- a. Remove vial and vial adapter from blue foam pouch.
- b. **Screw** white plunger rod to rubber plunger of pre-filled syringe. (**Fig. 1**)
- c. **Press firmly** and screw the **blue end** of the vial adapter into the **blue end** of the syringe connector. (**Fig. 2**)

NOTE: Do not force plunger. Syringe will not operate if vial adapter and syringe connector are not properly connected. Forcing plunger may result in syringe leakage and Mitosol[®] exposure.

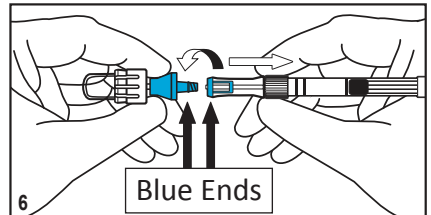
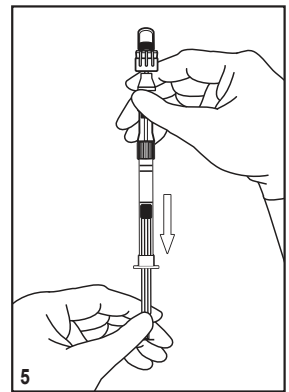


- d. Stand vial upright on a sturdy, flat surface and push on the vial lid until seated and secure. **(Fig. 3)**
- e. Inject entire contents of sterile water (1 ml) into vial. **(Fig. 4)** Do not force syringe plunger. See note at step 2.
- f. **IMPORTANT:** INVERT VIAL REPEATEDLY to saturate **ALL** drug product, including that adhering to stopper, then shake until complete reconstitution of Mitosol[®]. If product does not dissolve immediately, allow to stand at room temperature until the product has dissolved into solution.



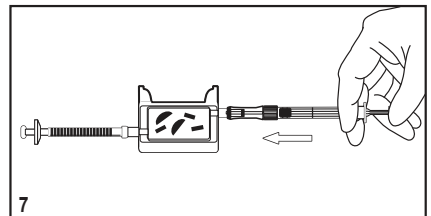
3. Preparing sponges

- a. **Invert vial and syringe** and draw full volume of medication into syringe. **(Fig. 5)**
- b. Remove all sponges from sponge tray.
- c. Return to sponge tray only those sponges to be saturated with Mitosol[®].
- d. Unscrew the syringe with safety connector from vial and vial adapter. **(Fig. 6)** Note: **DO NOT** remove safety connector from syringe.
- e. Place vial and vial adapter in chemotherapy waste disposal bag (yellow bag), and set bag aside, within sterile field, for additional use.
- f. Take sponge container from sterile inner tray.
- g. Screw both syringes into sponge container; the TB syringe to one end, the syringe with reconstituted Mitosol[®] to the other.



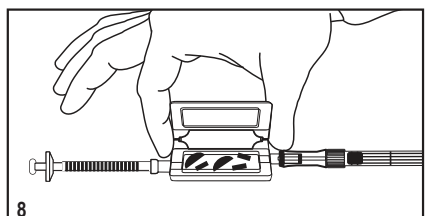
h. **Mitosol[®] must be used within 1 hour of reconstitution:**

- Inject medication into sponge container, saturating sponges. Reconstituted Mitosol[®] should remain undisturbed in sponge container for **60 seconds**. **(Fig. 7)** Do not force syringe plunger. See note at step 2.
- If any excess fluid remains, withdraw plunger of TB syringe, drawing excess fluid/air into syringe.



4. Using Mitosol[®]

- a. With both syringes connected, the TB syringe to one end, the pre-filled syringe to the other, open sponge container, offering contents to surgeon for placement on surgical site. **(Fig. 8)**
- b. Apply saturated sponges to surgical site for two minutes. Remove sponges from eye and copiously irrigate surgical site.



- c. As used sponges are removed from surgical site, accept used sponges back into sponge container for disposal. Close container lid.
- d. With syringes still connected to sponge container, remove entire assembly from surgical field in chemotherapy waste disposal bag.

DISPOSE OF CHEMOTHERAPY WASTE BAG AND ITS CONTENTS AS CHEMOTHERAPY WASTE

US Patents #7,806,265, #8,186,511, #D685,962, #D685,963, #9,205,075, #9,539,241 and #9,649,428; other international patents issued and pending.