

Mitosol[®]
(mitomycin for solution)
0.2 mg/vial
Kit for Ophthalmic Use

Read INSTRUCTIONS FOR USE Before Proceeding

Instructions for Use

A. Black Outer Pack
(Figure A)

- One Chemotherapy Waste Bag
- One Instructions for Use
- One Package Insert
- One Inner Tray

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



Figure A: Black Outer Pack

B. STERILE Inner Tray
(Figure B)

- One Vial Containing 0.2 mg mitomycin
- One 1 mL Syringe (Sterile Water for Injection) with Connector
- One Plunger Rod
- One Vial Adaptor with Spike
- One 1 mL TB Syringe, Luer Lock
- One Sponge Container
- Six 3 mm Absorbent Sponges
- Six 6 mm Absorbent Sponges
- Six Half Moon Sponges
- One Instrument Wedge Sponge
- One Alcohol Prep Pad, Sterile

*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.***

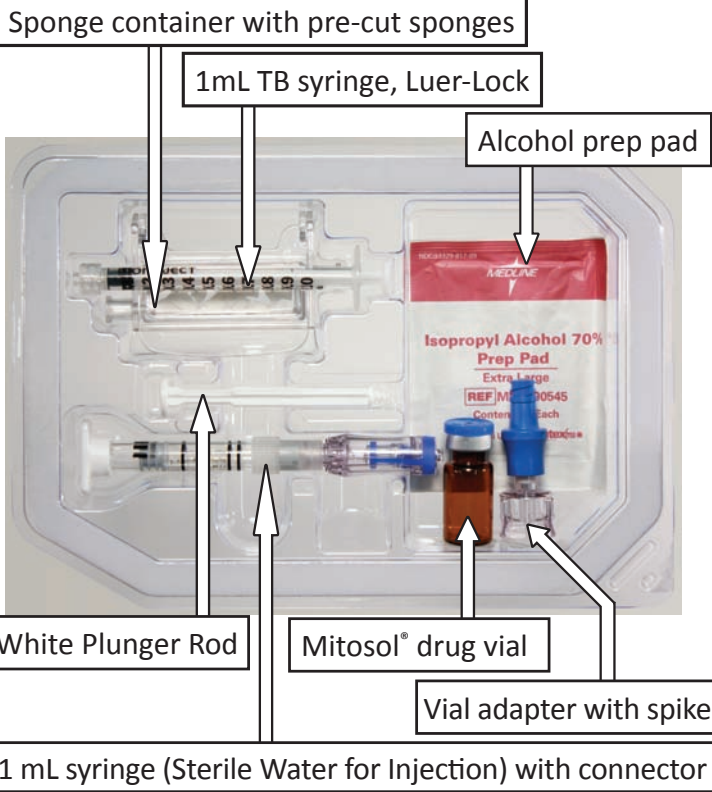


Figure B: Sterile Inner Tray

1. Getting Started

Non-Sterile Circulating Nurse:

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

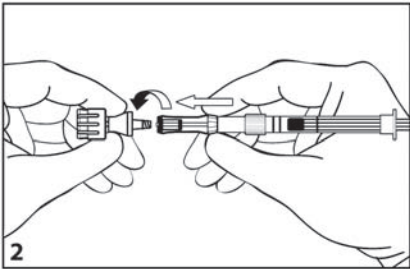
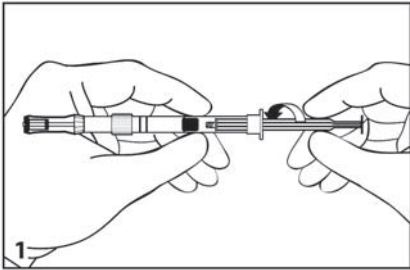
Sterile Surgical Technician:

Open sterile inner tray.

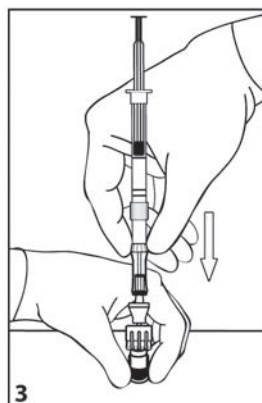
2. Reconstituting Mitosol[®]

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

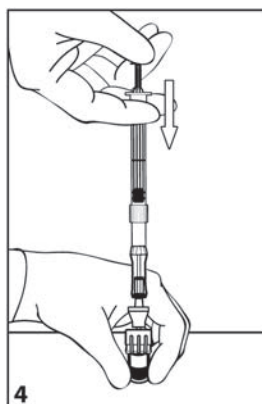
***NOTE:** For proper operation of the pre filled syringe, be sure it is fully and securely connected to a luer fitting. If it is not properly attached, the syringe will not operate. Excessive force applied to the plunger in this situation may force the contents to be expelled from the rear of the syringe.*



- c. Open and remove alcohol prep pad. Remove vial cap; disinfect vial stopper with alcohol prep pad.
- d. Holding vial face up, push spiked end of vial adapter down on the vial lid until seated and secure. **(Fig. 3)**

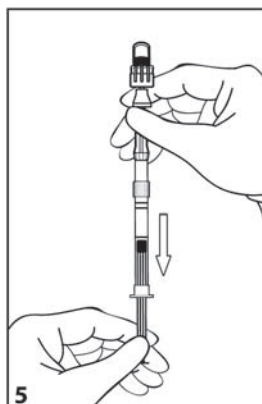


- e. Inject entire contents of sterile water (1 ml) into vial. **(Fig. 4)** *If syringe plunger does not operate, see note following step 2b.*
- f. Invert vial and shake until complete reconstitution of Mitosol®. If product does not dissolve immediately, allow to stand at room temperature until the product has dissolved into solution.

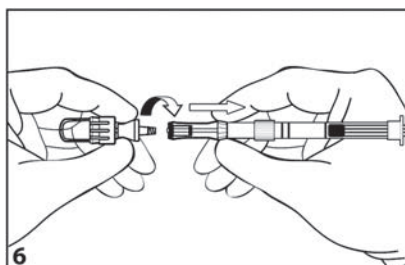


3. Preparing sponges

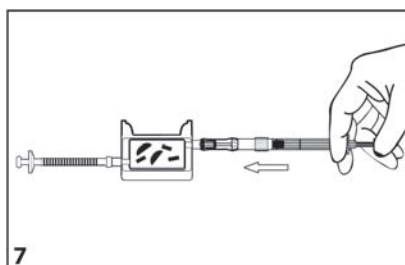
- a. ***Invert vial and syringe*** and draw full volume of medication into syringe.



- b. Unscrew the syringe and connector from vial and vial adapter (**Fig. 6**)
- c. Place vial and vial adaptor in chemotherapy waste disposal bag (yellow bag).
- d. Take sponge container from sterile inner tray.
- e. Screw both syringes into sponge container; the TB syringe to one end, the pre-filled syringe to the other.

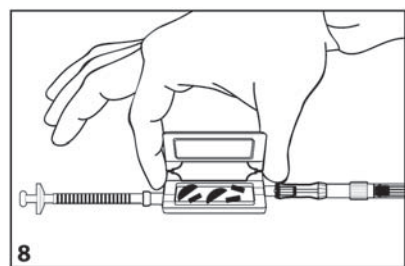


- f. MitoSol® must be used within 1 hour of reconstitution:***
- Inject medication into sponge container, saturating sponges. Reconstituted MitoSol® should remain undisturbed in sponge container for 60 seconds. **(Fig. 7)** *If syringe plunger does not operate, see note following step 2b.*
 - If any 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 back into 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