

Instructions for Use of the Multichamber Flexible Bag:

Multichamber Flexible Bag Use Instructions

Figure A

1 - Overwrap Notch

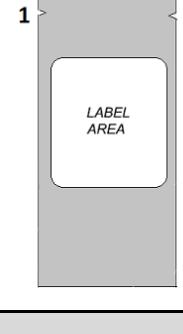
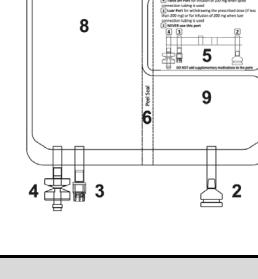


Figure B

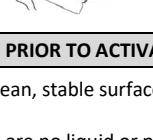
- 2 - NEVER use this port
- 3 - Luer Port
- 4 - Twist off Port
- 5 - Label Area
- 6 - Peel Seal (Must break to activate)
- 7 - Hole (For hanging the bag)
- 8 - Diluent chamber
- 9 - Lyophilized powder chamber



1 - REMOVE OVERWRAP

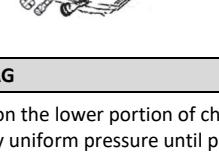
- a) Place bag on a clean, stable surface before opening.
- b) Tear from overwrap notch, located close to the ports (Figure A – point 1).
- c) Tear short sides open to access the inner bag as per Figure C.

Figure C



- d) Remove the multichamber flexible bag from the aluminum overwrap and unfold the bag Figure D.

Figure D



2 - INSPECT BAG PRIOR TO ACTIVATION

Place bag on a clean, stable surface with the ports pointing away from you, as per Figure E.

Check that there are no liquid or product leakages from the connection ports 2, 3, 4 and from the chambers 8, 9.

Check the integrity of peel seal 6, verifying the absence of liquid in the chamber 9.

Figure E



3 - ACTIVATE THE BAG

Overlap your hands, on the lower portion of chamber 8 (as per Figure F). Press firmly and apply uniform pressure until peel seal 6 is completely activated (it may take up to 5 seconds of continued pressure to break the peel seal 6).

Figure F



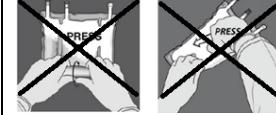
BAG BEFORE ACTIVATION

Figure G



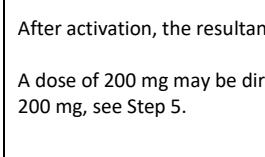
BAG AFTER ACTIVATION

Figure H



Do NOT squeeze.

Figure I



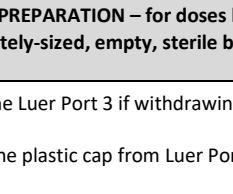
4 - INSPECT BAG TO CONFIRM ACTIVATION

Check the peel seal 6 is now completely activated.

Chamber 8 and 9 are merged.

If the bag is not activated, refer to Step 3.

Figure J

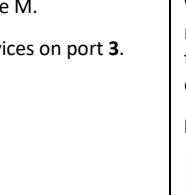


Mix gently until complete dissolution of product.

After activation, the resultant concentration is 1 mg/mL.

A dose of 200 mg may be directly infused from the bag (see Step 6). For doses less than 200 mg, see Step 5.

Figure K

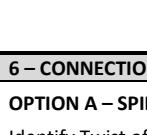


5 - DOSE PREPARATION – for doses less than 200 mg withdraw the patient-specific dose from the TEPADINA multichamber flexible bag and transfer to an appropriately-sized, empty, sterile bag for intravenous infusion.

Identify the Luer Port 3 if withdrawing a dose is needed.

Remove the plastic cap from Luer Port.

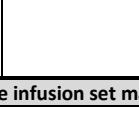
Figure L



Screw the luer lock device as per Figure M.

Do not use unproper non luer lock devices on port 3.

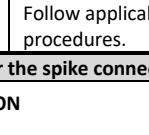
Figure M



Ensure that the connection is fully seated and tighten.

Withdraw the desired dose from TEPADINA bag. This may require multiple graduated syringes depending on the desired dose. Unscrew each syringe counter-clockwise when finished.

Figure N



Replace the plastic cap on the Luer-Lock port 3.

Attach a needle or an appropriate closed-system transfer device to each syringe containing thiopeta solution and transfer the contents to an appropriately-sized, empty, sterile bag for intravenous infusion.

Discard the unused portion of the TEPADINA bag. Follow applicable special handling and disposal procedures.

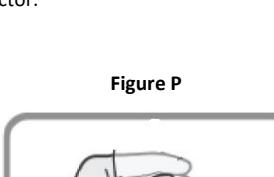
6 - CONNECTION for administration of 200 mg - The infusion set may be connected to the bag through either the spike connector OR the luer connector.

OPTION A – SPIKE CONNECTION

Identify Twist off port 4.

Twist off the plastic cap before inserting the spike.

Figure O

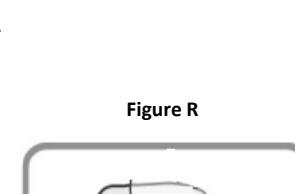


OPTION B – LUER CONNECTION

Select luer cap port 3.

Remove the plastic cap from luer port 3 before connecting the luer connector.

Figure Q



Insert the luer connector.

Figure P

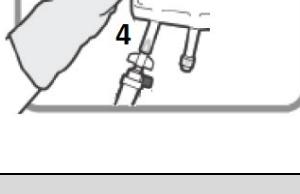
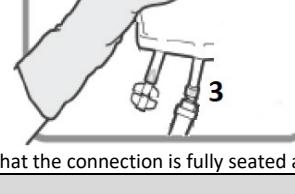


Figure R



Ensure that the connection is fully seated and tighten.

7 - HANG THE BAG

Hang the bag by the hole 7.

Figure S

