

Instructions for Use of the Multichamber Flexible Bag:

Multichamber Flexible Bag Use Instructions		
<div>Figure A</div> <div>1 - Overwrap Notch</div> <div><div>1</div><div>1</div><div>LABEL AREA</div></div>		<div>Figure B</div> <div>2 – NEVER use this port</div> <div>3 – Luer Port</div> <div>4 – Twist off Port</div> <div>5 – Label Area</div> <div>6 – Peel Seal (Must break to activate)</div> <div>7 – Hole (For hanging the bag)</div> <div>8 – Diluent chamber</div> <div>9 – Lyophilized powder chamber</div> <div><div><div>8</div><div>9</div><div>6</div><div>5</div><div>7</div><div>4</div><div>3</div><div>2</div></div></div>
1 – REMOVE OVERWRAP		
<div>a) Place bag on a clean, stable surface before opening.</div> <div>b) Tear from overwrap notch, located close to the ports (Figure A – point 1).</div> <div>c) Tear short sides open to access the inner bag as per Figure C.</div> <div>Figure C</div> <div><div></div></div>		<div>d) Remove the multichamber flexible bag from the aluminum overwrap and unfold the bag Figure D.</div> <div>Figure D</div> <div><div></div></div>
2 - INSPECT BAG PRIOR TO ACTIVATION		3 – ACTIVATE THE BAG
<div>Place bag on a clean, stable surface with the ports pointing away from you, as per Figure E.</div> <div>Check that there are no liquid or product leakages from the connection ports 2, 3, 4 and from the chambers 8, 9.</div> <div>Check the integrity of peel seal 6, verifying the absence of liquid in the chamber 9.</div> <div>Figure E</div> <div><div><div>2</div><div>3</div><div>4</div><div>9</div><div>6</div><div>8</div><div>7</div></div></div>		<div>Overlap your hands, on the lower portion of chamber 8 (as per Figure F).</div> <div>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).</div> <div>Figure F</div> <div><div><div>2</div><div>3</div><div>4</div><div>9</div><div>6</div><div>8</div></div><div><div></div></div></div>
BAG BEFORE ACTIVATION		BAG AFTER ACTIVATION
<div>Figure G</div> <div><div></div></div>		<div>Figure H</div> <div><div></div></div>
Do NOT squeeze.		<div>Figure I</div> <div><div><div></div></div><div><div></div></div></div>
4 – INSPECT BAG TO CONFIRM ACTIVATION		
<div>Check the peel seal 6 is now completely activated.</div> <div>Chamber 8 and 9 are merged.</div> <div>If the bag is not activated, refer to Step 3.</div> <div>Figure J</div> <div><div></div></div>		<div>Mix gently until complete dissolution of product.</div> <div>After activation, the resultant concentration is 1 mg/mL.</div> <div>A dose of 200 mg may be directly infused from the bag (see Step 6). For doses less than 200 mg, see Step 5.</div> <div>Figure K</div> <div><div><div></div></div></div>
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.		
<div>Identify the Luer Port 3 if withdrawing a dose is needed.</div> <div>Remove the plastic cap from Luer Port.</div> <div>Figure L</div> <div><div></div></div>	<div>Screw the luer lock device as per Figure M.</div> <div>Do not use improper non luer lock devices on port 3.</div> <div>Figure M</div> <div><div></div></div> <div>Ensure that the connection is fully seated and tighten.</div>	<div>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.</div> <div>Figure N</div> <div><div></div></div> <div>Replace the plastic cap on the Luer-Lock port 3.</div> <div>Attach a needle or an appropriate closed-system transfer device to each syringe containing thiotepa solution and transfer the contents to an appropriately-sized, empty, sterile bag for intravenous infusion.</div> <div>Discard the unused portion of the TEPADINA bag. Follow applicable special handling and disposal procedures.</div>
6 – CONNECTION for administration of 200 mg - The infusion set may be connected to the bag through either the spike connector <u>OR</u> the luer connector.		
<div>OPTION A – SPIKE CONNECTION</div> <div>Identify Twist off port 4.</div> <div>Twist off the plastic cap before inserting the spike.</div> <div>Figure O</div> <div><div></div></div> <div>Insert the spike connector.</div> <div>Figure P</div> <div><div></div></div>		<div>OPTION B– LUER CONNECTION</div> <div>Select luer cap port 3.</div> <div>Remove the plastic cap from luer port 3 before connecting the luer connector.</div> <div>Figure Q</div> <div><div></div></div> <div>Insert the luer connector.</div> <div>Figure R</div> <div><div></div></div> <div>Ensure that the connection is fully seated and tighten.</div>
7 – HANG THE BAG		
<div>Hang the bag by the hole 7.</div>		<div>Figure S</div> <div><div></div></div>