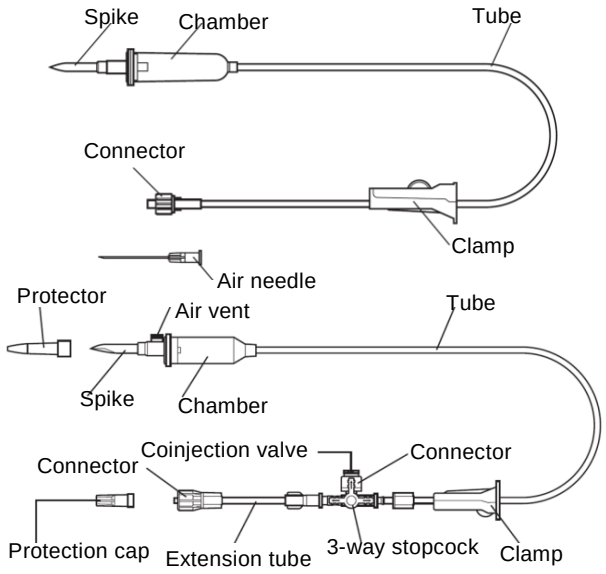
(Nonreusable)

TOP SOLUTION INFUSION SET

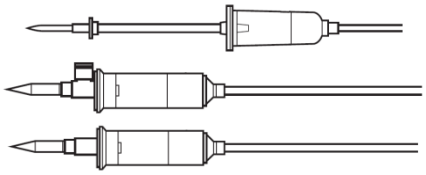
[Warning]
- Prior to coinjection, be sure to disinfect the coinjection valve with cotton or the like impregnated with alcohol for disinfection (or povidone-iodine). [The coinjection valve may be contaminated with bacteria.]

[Contraindications and Prohibitions]
- Do not reuse.
- Do not use a needle to perform coinjection. [This may damage the coinjection valve, resulting in leakage or contamination.]

[Shape, Structure, and Principle]
<Structural drawing (main)>



- Shapes of spike and chamber.



- Variety: with 3-way stopcock or Y-site or Filter etc.
- Tube: DEHP Free or PVC free

Material (DEHP Free)

Spike	ABS or Polycarbonate
Chamber	Polyvinylchloride or Polypropylene
Tube	Polyvinylchloride
Rubber tube	Isoprene rubber
Bubble catcher	Polypropylene
Connector	Polyvinylchloride
Needle	Stainless steel
Needle hub	Polypropylene
Winged Infusion Set (Needle)	Stainless steel
Winged Infusion Set (Wing/Tube)	Polyvinylchloride
3-way stopcock (Body)	Polycarbonate
3-way stopcock (Handle)	Polyethylene
Y-site (Body)	Polyvinylchloride
Y-site (Rubber cap)	Isoprene rubber

- This product uses polyvinylchloride (plasticizer: trioctyl trimellitate).

Material (PVC free)

Spike	ABS or Polycarbonate
Chamber	Polypropylene
Tube	Polybutadiene or EVA / Polybutadiene (Two-layer structure)
Connector	Nylon
3-way stopcock (Body)	Polycarbonate or Polypropylene
3-way stopcock (Handle)	Polyethylene
Valve	Silicone rubber
Filter (Body)	Polyester
Filter (Membrane filter)	Polyether sulfone
Filter (Air-bleeding filter)	Polyvinylidene fluoride

[Usage and Indication]
- This product is used for intravenous infusion of intravenous drug solutions.

[How to Operate, and Dosage and Administration]
<Priming step>
1. Puncture an air needle vertically into the rubber stopper of the infusion bottle at a predetermined position.
- This operation is not needed for soft bag or the spike with air vent.
2. As necessary, coinject a drug solution to infuison bottle.
3. Completely close the clamp of the infusion set and puncture deeply the spike to a predetermined position of infusion bottle vertically.
- For spike with air vent, in the case of glass infusion bottles or semi-rigid plastic bottle, open the vent cap to infuse. In using a soft bag and connecting tube, close the vent cap to infuse.
- Puncture the spike slowly and straight into the rubber stopper. Also, do not puncture the same location repeatedly. [Rubber pieces may get mixed in this product.]
- Do not insert the spike diagonally into the rubber stopper or apply lateral force during insertion. [The spike may be bent or damaged.]
4. Hang the infusion bottle which infusion set connected to, and gently press the chamber with your finger to enter the drug solution. Repeat this operation to fill the drug solution up to about half of the chamber to prevent air contamination.
- If this product is mounted to Infusion pump, fill the drug solution up to about one third of the chamber.
5. Open the clamp and fill up to the tip of the venous needle with the drug solution. After the air in the tube is completely released, close the clamp again.
- Use the drug solution after acclimatizing the room temperature, and do no perform the priming that causes bubbles in the chamber. Unless otherwise specified in the package insert of the drug or medical device to be used in combination, fill up to about half of the chamber with drug solution and be careful of the drop in the liquid level. If this product is mounted to Infusion Pump, fill the drug solution up to about one third of chamber. [Inclusion of air may be occurred.]
- Do not lie or tilt the chamber after priming. Also, do not empty the chamber in replacing the infusion container or during infusion. [Inclusion of air may be occurred.]
- Do not perform clamp operation at the connection between the tube and other parts. [The tube may be bitten by the clamp and break.]
- If there is no venous needle from the beginning and the

venous needle is connected to the connection part, perform the air-bleeding after connection.
- Be careful not to damage the tip of the venous needle by contact of protector or solid matter.
- Be careful that the vein needle of the type with a vein needle cannot be connected to a syringe or other infusion set.
- Please note that the drug solution may not drip normally if air is included in the tube.
- Check that the connection part is not loose.

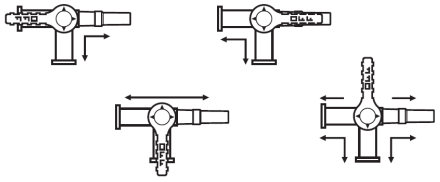
6. After checking that the venous needle is firmly connected, pull out the protector of the venous needle straight to remove, puncture in the blood vessel and fix this product.
- If there is no venous needle, connect to Winged infusion needle or IV Catheter which have already been placed in the blood vessel.

7. When an infusion pump is used for infusion, mount the tube of this product along the tube guide of the infusion pump and set the infusion conditions.
8. Gradually open the clamp, adjust the speed while watching the drip state and start infusion.

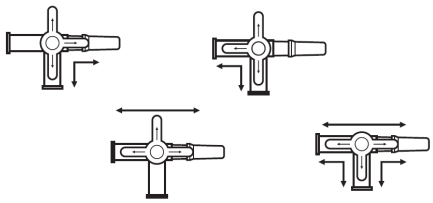
<Precautions concerning Use>
- Before using a connector with a lock connector, make sure that the connector is not loose.
- Do not apply excessive tensile force to the product or excessive stress to the connections. Use sufficient care to ensure that the patient does not crush the infusion line with his or her body motion. [The connection may be damaged, loosened or removed.]
- At the beginning of infusion, be sure to check the infusion status (drip drop, liquid level in chamber, decrease in infusion) and puncture site. Also, periodically conduct the similar check during infusion too.
- In closing the clamp, make sure that the tube is securely occluded.
- There are two types of chamber, one for general use and the other for small amount, and the number of drops per 1 mL (dropping amount) is different. So, check the number of drops displayed on the package before use.
- Do not use the infusion pump with the drop number setting different from the drop number display (displayed on the package) of this product. [If the infusion pump with different number of drops is used, the volume of infusion may be different.]
- In administering by a drip method (weight type infusion, drip control type pump etc.), be noted that the volume per drop may vary depending on the drug solution.
- Be careful not to touch the air needle, spike and venous needle directly by hand. Also, be careful about needle stick during and after use.
- In using an infusion pump, be sure to attach to the infusion pump and perform the infusion operation according to the operation guide for infusion pump. [Insufficient mounting will affect the accuracy of infusion volume, false alarm of air bubble detection and occlusion detection pressure.]
- If using rubber tubing, do not apply excessive force or tension. Also, be careful not to occlude the line when using the infusion pump. [Since the part is not adhered, the connection part may come off.]
- When used with infusion pump that does not have an air bubble detection function, stop the infusion before the liquid in the infusion solution container runs out.
- When used with infusion pump that does not have an occlusion detection function, excessive pressure may be applied due to occlusion of the infusion line, which may cause disconnection and damage of the connection.
- When an infusion pump is used for infusion, the tube may be deformed and the flow rate may become inaccurate. So, the pump mounting position of the tube is displaced or replaced with a new infusion set every 24 hours. [The tube may be deformed or damaged.]

● **Manipulation of Y-site (for any variety with Y-site)**
<Precautions concerning Use>
- For coinjection rubber, puncture with the needle vertical.
- Do not use after removing coinjection rubber.
- In performing coinjection from Y-site, consider the property of the drug solution and as necessary, take appropriate measures such as flushing with saline before and after coinjection. [Since Y-site has a structure laterally branched from the flow path of the infusion solution, a part of the drug solution may remain.]

● **Manipulation of 3-way stopcock (for any variety with 3-way stopcock)**
- Flow direction: Determined by handle position



Type L(360˚)

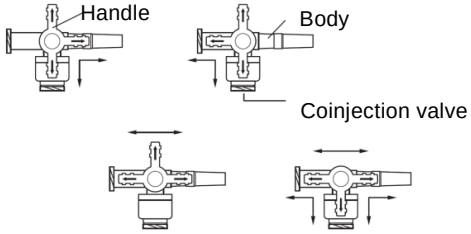


Type R

<Precautions concerning Use>
- In connecting a syringe, a connector etc to 3-way stopcock, ensure that it is firmly connected to prevent a disconnection. Check that the handle is manipulated so as to select the flow direction.
- When the cap for coinjection is fit to 3-way stopcock and coinjection is performed using a needle, the needle tip may come into contact with the handle and damage the handle, resulting in leakage.
- In coinjecting drug solutions through 3-way stopcock, pay attention to inclusion of air.
- To suspend fluid infusion or remove an infusion set, an extension tube from the female taper of the 3-way stopcock, connect the dedicated protection cap to ensure sealing. [Opening of the female-taper part may cause leakage, inclusion of air or contamination.]
- To coinject drug solutions through 3-was stopcock, as necessary, take appropriate measures such as flushing with saline before and after coinjection. [A part of the drug solutions may remain in the stopcock because of its branching structure.]

● **Manipulation of 3-way stopcock NL type (for any variety with 3-way stopcock NL type)**

• Flow direction: Determined by handle position



Type R

<Coinjection step>

1. Disinfect the coinjection valve with a disinfectant.
2. Securely connect the male luer taper connector of a syringe, an infusion set etc to the coinjection valve of this product.
3. Securely lock a lock type male luer taper, and start coinjection. For a non-lock type, securely hold this product and a syringe or the like by hand and then perform coinjection while ensuring that they are not disconnected.
4. After finishing the coinjection steps, securely hold the product by hand and then remove the syringe, infusion set etc.

<Precautions concerning Use>

- In connecting the coinjection valve, the male luer taper with lock type is recommended.
- In the connecting the male luer taper with the non-lock type, connect or remove straightly. Do not connect the male luer taper too deeply. It is also prohibited to connect or disconnect the male luer taper while twisting it or while tilting the syringe etc. [The valve (silicone) may be cracked, resulting in leakage or depression of the valve.]
- If any valve depression is found, immediately replace with new product.
- In connecting a syringe or removing it from the coinjection valve, be sure to check that there is no depression of valve. [Leakage, obstruction, infection etc may occur.]
- For continuous coinjection to the coinjection valve, use the male luer taper with lock type. [The valve may be depressed or damaged by coming off the connection or maintaining it for a long time in a state where it is inserted deeper than necessary.]
- For connection to the coinjection valve, be sure to check that a flow path has been secured. [If the male luer taper is out of specification or the connection is insufficient, the coinjection valve may not open and the drug solution may not flow.]
- In connecting to the coinjection valve, the valve may be occluded depending on the tip shape of the male luer taper, so be sure to check that the flow path is secured. If the solution does not pass, reconnect it. If the solution does not pass even after reconnecting, do not use this product. Also, if you cannot confirm the liquid flow due to a small amount of injection using a syringe pump, do not use this product.
- After finishing coinjection, flush with saline etc to prevent blood coagulation and crystallization of the drug solution. [The valve may damage.]
- In coinjecting drug solutions, take care about the inclusion of air.
- To remove the product from the syringe after finishing the coinjection operation, securely hold the body of the product by hand while taking care to ensure that the other connections are not loosened.
- After connecting a male luer taper to the coinjection valve, do not apply excessive load laterally. [The coinjection valve may be damaged.]
- To coinject drug solution, consider the property and as necessary, take appropriate measures such as flushing with saline before and after coinjection. [A part of the drug solutions which have been coinjected may remain in the product because of its branching structure.]
- If the coinjection valve shows crack, damage, loosening, or any other anomaly, replace it.
- Prior to coinjection, be sure to disinfect the coinjection valve with cotton or the like impregnated with alcohol for disinfection (or povidone-iodine). During this process, take care to ensure that the body of this product is not exposed to the disinfectant. Do not disinfect the product by immersing it in any disinfectant. [Cracking may occur, causing leakage.]
- Do not directly touch the coinjection valve.
- If the coinjection valve is contaminated, replace it.
- If internal pressure applies to the coinjection valve, leakage may occur. Therefore, ensure that no internal pressure applies to the coinjection valve.
- When a connector or the like is connected to the product, do not excessively tighten it. [The connection may be damaged.]

● **Manipulation of filter (for any variety with filter)**

<Precautions concerning Use>

- In using the filter or stopping the infusion temporarily, be sure to tighten the clamp below the filter.
- The infusion filter must be fixed below the patient's heart. Be aware that if it is fixed at a position higher than the heart, air may be drawn in through the air vent of the filter.
- Make sure that the drug solution that easily adsorbs passes through the filter before use.
- If the filter surface is colored, the clogging of the filter may be occurred, so replace it.
- Emulsion drugs such as fat emulsion and blood products do not pass through the filter. In administering these drugs, perform from the coinjection valve below the filter.
- If a drug solution containing a surfactant such as a multivitamin preparation is used, the air vent filter may be hydrophilized and leakage may occur. When the air vent filter becomes transparent, replace it immediately.
- Avoid suction from the top of the filter and pressurization from the bottom of the filter. Also, do not apply a pressure of 98 kPa or more during injection. [Excessive pressure may damage the filter (air vent).]

[Precautions]

<General>

- Prior to use, ensure that this product is connected certainly to other extension tube, winged infusion set, IV catheter. And, periodically check the product for any damage, loosened connection, or leakage during use.
- Do not apply excessive tensile force to the product or excessive stress to the connections. [The connection may be damaged.]
- Pay attention to tightening and re-tightening with a drug solution attached to the connection part. [The connection part becomes deeper than usual and does not come off or is damaged.]
- If a drug solution or blood adheres to the connector, the connector may be loosened.
- Do not clamp the tube with forceps or the like and ensure that the tube is not damaged with scissors or a cutting tool. [Leakage, inclusion of air or damage to the tube may result]

- The filter screen and infusion filter attached to the air catcher may be clogged, so check them regularly. Immediately replace with new product if clogging is confirmed. [Clogging may occur due to changes in the formulation of the drug solution, deposits, backflow of blood and so on.]
- For a small quantity (60 drops≒1 mL) chamber, do not immerse the minute drip mouth inside the chamber in the drug solution, such as tilting the chamber after priming. Also, during use, check regularly whether the amount dropped becomes large. [Depending on the type of drug solution (including surfactant etc), the minute amount drip mouth part is gradually made hydrophilic and the volume per drop becomes large, it may cause overdose.]
- When using the infusion pump for infusion, do not use this product in an environment below 10 ° C. [Increased tube hardness may result in inaccurate flow rates in using infusion pumps.]

<Interactions with Drug and Medical device>
- To administer fat emulsion or a drug containing fat emulsion, an oily component such as castor oil, or a drug containing solubilization agent such as surfactant and alcohol or to use a disinfectant containing alcohol, check the 3-way stopcock, connector, female connector, etc. for any crack. [The drug solution may cause the 3-way stopcock and connectors such as an, extension tube to crack, resulting in leakage of blood and the drug solution or inclusion of air. In particular, when you give general anesthesia or administer a vasopressor, anticancer drug, or immunosuppressant, it may inhibit administration of required dosage and may have serious effect on the patient. Retightening or excessive tightening when changing a line may accelerate cracking.]
- If you find any crack, immediately replace the product.

<Defects and adverse events>

1) Other defects
   Contamination (damage to package etc), tube breakage, breakage (excessive load etc), connection failure (looseness, leakage, air inclusion, sticking), connectiondamage (excessive stress etc), tube constriction (bending or pinching etc), filter clogging (medicine etc), hydrophilization of filter, free flow, underdose, overdose
2) Other adverse events
   Infection, thrombosis, air embolism

[Method of Storage and Expiration Date]

<Method of storage>
- Store the product while keeping it from wetting. It should be kept from high temperature, high humidity, and direct sunlight.

<Expiration date>
- See the expiration date field on the inner box.
  (To be set by self-authentication)

Manufacturer :
TOP Corporation
19-10 Senju Nakai-cho, Adachi-ku, Tokyo 120-0035, Japan

Manufacturing Facility :
MEDITOP CORPORATION (MALAYSIA) SDN. BHD.
Lot 1, Jalan P/1B, Kawasan Perindustrian Bangi,
43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia

For Malaysia market
Auth. Rep. :
MEDITOP CORPORATION (MALAYSIA) SDN. BHD.
[BRN: 198901006508 (183811-X)]
Tel: +603-89240999 / E-mail: sales@meditop.com.my

MDA Reg. No. GB18629247917

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