Instructions for use

Contraindicated to re-use

[CONTRAINDICATIONS • PROHIBITION]

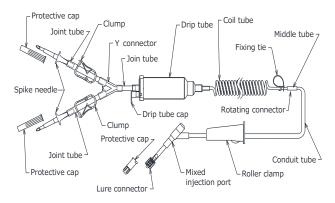
Do not reuse the product (single use only).

[Shape, structure, principle]

This product is sterilized with ethylene oxide gas.

• This product (joint tube, middle tube, conduit tube, Y connector drip tube) uses polyvinyl chloride (plasticizer: di (2-ethylhexyl) phthalate).

<Shape>



Coil tube length	Conduit tube length	Drip amount
3500 to 4000mm	1150mm	20 drips≒1mL
(When extended)		

<Raw Materials>

Part name	Material name	
Spike needle	ABS resin	
Protective cap	Polyethylene	
Clump	Polypropylene	
Joint tube Middle tube Conduit tube	PVC	
Y connector	PVC	
Drip tube	PVC	
Drip tube cap	Silicone rubber	
Coil tube	Polyurethane	
Fixing tie	Nylon	
Roller clamp	Polyacetal	
Mixed injection port	ABS resin, Isoprene rubber	
Lure connector	Polycarbonate	
Protective cap	Polypropylene	

<Principles>

The drug solution is administered by a spontaneous drip method without using a pump.

[Intended purpose, efficacy or effect]

Inject large amounts of injectable medicines without using syringe.

[Operating or using method]

The below is a general procedure.

- Open the product hygienically, completely close the two clamps and the roller clamp.
- [2] Remove the protective cap on one of the spike needles.
- [3] With the infusion container outlet facing up, insert the spike needle straight

into the center of the rubber stopper of the container to a full depth. When connecting to 2 infusion containers, repeat steps [2] to [3].

- [4] Hang the infusion container to which this product is connected and loosen the clamp, squeeze the drip tube gently with your finger to release, fill the drip tube with the drug solution to about 1/2. (Priming operation)
- [5] Connect an appropriate indwelling needle to the male connector.
- [6] Loosen the roller clamp, fill the tip of the indwelling needle, etc., remove the air in the tube, and close the roller clamp again.
- [7] Puncture the indwelling needle into the blood vessel and gradually loosen the roller clamp while observing the infusion state and adjusting the infusion rate. The infusion rate should be continuously monitored and if it changes in the infusion rate, adjust the roller clamp.
- [8] When using the mixed injection port, puncture the rubber stopper of the mixed injection port vertically with a sterilized needle.
- [9] When draining the infusion solution in the drip tube, remove the drip tube cap and drain, put the cap firmly after discharging.

<Precautions for the using method>

[1] Always perform visual inspection the appearance of the product before use.

- [2] Use immediately after opening the package.
- [3] When connecting to a vein indwelling needle, etc., tighten firmly so that it will not come loose or come off.
- [4] When using spike needles, indwelling needles or etc., please observe the following items.
 - Do not touch the needles such as spike needles and indwelling needles directly.
 - · When removing the cap, make sure not to touch the tip of the needle.
 - If a rubber stopper such as an infusion container etc. is punctured diagonally or a force is applied in the lateral direction, the spike needle or etc. may be bent or damaged.
 - When puncturing the infusion container, make sure not to let the needle tip come in contact with the wall surface of the infusion container.
 - When puncturing the infusion container with a spike needle, puncture the rubber stopper straight and slowly. Do not puncture the same place repeatedly.

[Rubber pieces may get mixed in the set components.]

- [5] In the mixed injection operation, the puncture needle is inserted vertically into the mixed injection rubber (rubber stopper of the mixed injection port).
- [5] Check for drug solutions, etc. adhering to the connection. [Looseness of the connection part may occur.]
- [7] When using the clamp, make sure that the tube does not come off inside the clamp and the clamp can be adjusted.

[The rollers may come off or the flow rate may not be adjustable.]

[8] If any abnormality such as liquid leakage from the connection is found during priming, stop using immediately.

[Precautions]

<Important basic caution>

- Before mixing with a needle, be sure to disinfect the mixed injection site with alcohol-soaked (or povidone iodine-soaked) cotton.
 [Bacteria may be mixed]
- [2] Note that di (2-ethylhexyl) phthalate, which is a plasticizer for polyvinyl chloride, may elute in fat-soluble pharmaceuticals or chemicals. When using medicines, drug solutions or etc., check the package inserts before using.

[This product uses polyvinyl chloride.]

[3] When administering a defatted emulsion, a drug containing a defatted emulsion, an oily component such as castor oil, a surfactant or a solubilizing agent such as ethanol, etc., and when using a disinfectant containing ethanol, make sure to confirm cracks in the outer cylinder and

connectors.

- [There is a possibility that the outer cylinder, connector, etc. may be cracked by the drug solution, causing blood and drug solution leakage, air contamination and etc. Re-tightening, excessive tightening, and retightening when replacing the line are caused the occurrence of cracks.]
- [4] If cracks are found, replace with a new product immediately.
- [5] Do not use if the packaging is damaged or soiled, the product is damaged, otherwise abnormal or etc.
- [6] Open the package just before use.
- [7] Make sure to confirm that the product is the intended product when using.
- [8] After checking the package inserts of the medicines and medical devices to be used in combination, use according to the respective usage methods and precautions.
- [9] When administering by the drip method (gravity type infusion), note that the volume per drip may differ depending on the drug solution.
- [10] At the start of the drug solution, check the infusion status such as the drop status of the drip, the height of the liquid level in the drip tube, and the puncture site.
- [11] Allow the drug solution to acclimatize to room temperature before use. Do not perform a priming operation that causes the inside of the drip tube to foam. If the package insert of the drug solution or medical device to be used in combination does not specify, the drug solution should be stored up to about half of the IV tube and the liquid level should be lowered. [Air may be occur and mixed in the tube.]
- [12] Do not lay or tilt the IV tube after priming. Do not empty the IV tube when replacing the infusion container and during infusion. [Air may be mixed in the tube, difficult for the drug solution to flow.]
- [13] Before using, make sure that no looseness or liquid leakage in the connection part. During use, check regularly for damage to this product, loose connections, air contamination, drug solution leakage and clogging.
- [14] Administer the drug solution immediately after priming. [The drug solution may be contaminated.]
- [15] Do not use the tube in a bent or pulled state.
- [16] Make sure not to get the tube etc. caught under the animal body. [The tube, etc. may be broken, blocked, or damaged.]
- [17] Do not to damage the tube by pinching with forceps. [Drug solution leakage, air contamination or damage may occur.]
- [18] Do not operate the clamp near the joint between the tube and a hard part (connector, etc.).

[The tube may get caught in the clamp and break.]

- [19] Do not to apply excessive pulling, pushing, or bending loads to the connection between the tube and the connector. [The tube may come off, break, stretch, etc.]
- [20] When connecting the connector, do not overtighten. [The connector may not come off or may be damaged.]
- [21] When using a rubber stopper, do not apply excessive pushing and pulling pressure. Note that the drug solution infiltrates due to the load such as distortion etc. and the bonding strength decreases.[Since the part is non-adhesive, the joint part may come off.]
- [22] Pay attention when handling at low temperatures because it is a plastic product.

[Damage to the drip tube, etc. may occur.]

- [23] After priming, the drip tube may become cloudy white, but this is a phenomenon caused by the characteristics of the material of the drip tube and no problem in performance.
- [24] When mixed injection using a needle, make sure that the needle tip does not come in contact with the cock, etc.
- [The cock etc. may be damaged and the drug solution may leak.] [25] Do not contaminate the wetted parts.
- [26] Do not use the one has expired.
- [27] Do not remodel the device.
- [28] Do not expose the device to drugs classified into a strong acid or a strong alkali and organic solvents.
- [29] Do not pinch the device with forceps too strongly. [The tube may be broken or lumen may be occluded.]
- [30] Pay attention to infection prevention for this product after use and dispose

the device by a safe method. When covering the indwelling needle with a cap, make sure not to accidentally pierce or the needle pops out of the cap.

<Failures • Adverse events> Failures

- The following failures may be caused by the use of the product:
- [1] Drug solution leakage
- [2] Damage to the product.
- [3] Cut of the catheter.
 - [Cut due to the following causes]
 - · Damage caused by forceps, scissors, knife or other apparatuses
 - · Sudden load on the product such as accidental removal.
 - · Other combined causes due to the above causes.

Adverse events

- The following adverse events may be caused by the use of the product:
- [1] Infectious disease
- [2] Contamination of drug solutions from the connection
- [3] Air inhalation from the connection part and air blockage due to inhaled air injection

[Storage conditions and duration of use]

<Storage conditions>

Store the product hygienically, avoiding the direct sun light, high humidity and ultraviolet rays such as a sterilizing lamp and taking care of wetting.

< Expiration date >

See the expiration date given on each package provided that the device is stored appropriately.

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