

EVA INFUSION BAG INSTRUCTIONS FOR USE

| PORTS OF EVA BAG | | | | |
|--|--|--|-------------------------------------|---|
| EVA INFUSION BAGS w. FL L/MLL LUER CONNECTOR | EVA INFUSION BAGS w. BIGBORE CONNECTOR | EVA INFUSION BAGS w. NEEDLE-FREE CONNECTOR | EVA INFUSION BAGS w. EXTENSION LINE | EVA INFUSION BAGS w. 3/6 - WAY TRANSFER SET |
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RELATED PRODUCTS

UV protected or transparent EVA bags containing various types of connectors or extension lines at the port end

PRODUCT DESCRIPTION

EVA infusion bags are sterile - disposable bags in the structure of Ethylene Vinyl Acetate, in which sterile drugs or liquids are filled and administered to the patient with the help of an administration set.

INSTRUCTIONS FOR USE

- Remove the EVA bag from its sterile package by using aseptic technique.
- On the clamp port of the EVA bag;
 - For EVA INFUSION BAGS w. FLL/MLL LUER CONNECTOR: Remove the cap from the FLL/MLL filling port.
 - For EVA INFUSION BAGS w. BIG BORE CONNECTOR: Remove the cap from the Big Bore filling port.
 - For EVA INFUSION BAGS w. NEEDLE – FREE CONNECTOR: Remove the cap from the valve end.
 - For EVA INFUSION BAGS w. EXTENSION LINE: Remove the cap on the spike end of the extension line.
 - For EVA INFUSION BAGS w. 3/6 – WAY TRANSFER SET: Remove the cap on the spike end of the extension line as much as the number of source container to be used.
- In order to perform the filling;
 - For EVA INFUSION BAGS w. FLL/MLL LUER CONNECTOR: Attach one end of the drug transfer set to the MLL/FLL port of the EVA bag and the other end of the drug transfer set to

the source container to be used in drug preparation and perform the pre-filling process.

- For EVA INFUSION BAGS w. BIG BORE CONNECTOR: Attach one end of the drug transfer set to the Big Bore port of the EVA bag and the other end of the drug transfer set to the source container to be used in drug preparation and perform the pre-filling process.
 - For EVA INFUSION BAGS w. NEEDLE – FREE CONNECTOR: Attach one end of the drug transfer set to the Vein Valve port of the EVA bag and the other end of the drug transfer set to the source container to be used in drug preparation and perform the pre-filling process.
 - For EVA INFUSION BAGS w. EXTENSION LINE: Attach the spike end of the extension line to the bag/vial to be used as the source container and perform the pre-filling process.
 - For EVA INFUSION BAGS w. 3/6 – WAY TRANSFER SET: Attach the spike end of the transfer set to the bag/vial to be used as the source container and perform the multi-filling process. Remove the cap on the spike ends of the transfer set as much as the number of source container to be used and attach to the relevant source container.
- After filling is complete, close the clamp on the EVA bag and disconnect the drug transfer set. Re-close the cap that was removed before the procedure.
 - For contents that need to be added by syringe, break the injection port. Transfer the medicine from the syringe to the bag by entering the injection port with the needle tip. Close the injection port cap when the transfer

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process is complete. The bag is ready for drug administration.

- Depending on the feature of the administration set to be used during the infusion, attach the administration set to the spike administration port or one of the luer/big bore/vein valve administration ports and administer the drug.
- Follow the instructions for use of the infusion set.
- After the medication administration process is completed, dispose of the EVA Bag according to the hospital's medical waste process.

WARNINGS & PRECAUTIONS

- It should be used by healthcare personnel.
- DO NOT USE if the package has been opened or damaged.
- DO NOT USE expired products.
- Check that all protective caps are present before use.
- DO NOT ACCESS needle-free valves with a needle or blunt cannula.
- DO NOT USE in patients who are hypersensitive to any of the materials used.
- If the silicone part of the valve becomes damaged or does not return to its original form after multiple access, replace the product. This may cause leakage.
- DO NOT OVERTIGHTEN the connections.
- If it is leaking, replace the product with a new one.
- Replace the product with a new one in case the set separates from the bonding areas.
- The product is for single use only. DO NOT RESTERILIZE.
- DO NOT LEAVE infusion sets unattended.
- If you observe that a drug or liquid has damaged the product, replace product with a new one and inform our company by naming the drug.
- When the drug filling & administration process is finished, dispose of the products as a whole without separating the bag from administration set.
- Follow local regulations regarding the disposal of hazardous drugs.
- The healthcare personnel (the nurse or biologist who prepared the drug) decides on the use of a transparent or UV-protected infusion bag, depending on the light protection requirement of the content (drug) to be used. Transparent or light-protected bags are used depending on the content to be used.

STORAGE TEMPERATURE

Product storage temperature is 15 – 30°C.












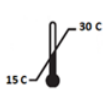






SHELF LIFE

The shelf life of the product is 5 years.

USERS

Specialist physicians, nurses, pharmacists and other relevant health-trained workers.

LABEL DISCLOSURES

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|  |  |  |  |  |
| Manufacturer Information | Notified Body Number | Manufacturing Date | Expiry Date | Lot Number |
|  |  |  |  |  |
| Reference Number | Sterilized with EO Gas | Do Not Re-sterilize | Do Not Use If Package is Damaged | Keep Away From The Sun |
|  |  |  |  |  |
| See User Manual | Storage Temperature Limits | Single Use Only | Caution | Pyrogen Free |
|  |  |  | | |
| DEHP – Free | Latex – Free | Medical Device | | |