ACD – A ANTICOAGULANT SOLUTION
USER INSTRUCTIONS

CE 1008

SYSTEMS THAT THE USER INSTRUCTIONS ARE APPLICABLE

2******6525	KANSUK ACD-A ANTİCOAGÜLANT SOLUTION, 500ML
2******6524	KANSUK ACD_A ANTİCOAGÜLANT SOLUTION, 1000ML

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DEFINITION
The solution is presented in 500 ml PVC bags wrapped in transparent package.
Every 100 ml contains;
- 2,45 gr Glucose Monohydrate
- 2,2 gr Sodium Citrate Dihydrate
- 0,73 gr Citric Acid Monohydrate
- Water for injection

INDICATIONS
- ACD-A solution is used as anticoagulant solution during collection of blood in apheresis devices.

GENERAL PREPARATIONS BEFORE USAGE
- Before opening blood bag systems, control the overwrap in terms of including tear or puncture.
- After opening the overwrap, control the blood bag in terms of including tear or puncture.

INSTRUCTIONS FOR USE
- Open the outer wrap of the solution by pulling from its corner
- Inspect the bag for any defects.
- Use transfusion set compatible with ISO EN 1135-4. If the solution will be connected to a device, connect the solution according to the device manufacturer instructions.
- Hold the top part of the T port with one hand and bag from the bottom part of T port with other hand, and twist of the upper part by 270°C (see figure 1)
- Keep holding the bag from bottom part of the T port, Remove the cap of the transfusion spike with other hand.
- Insert the spike by 3/4 of its length into outlet port. Do not touch the spike of the transfusion set and open outlet port to prevent contamination
- After inserting the spike, squeeze the bag to the level that transfusion set filter is filled with blood.
- Hook the bag from its bottom holder.

CAUTIONS AND PRECAUTIONS:
- Patients or donors that have ruined or abnormous citrate and/or calcium metabolism may show risk of increasing citrate sensitivity. The doctor carrying out the treatment should evaluate the suitability of such patients or donors for apheresis and should indicate how they should be monitored during apheresis process.
- For overall list of cautions, precautions and undesired effects, please look at the apheresis device guide for the operator.

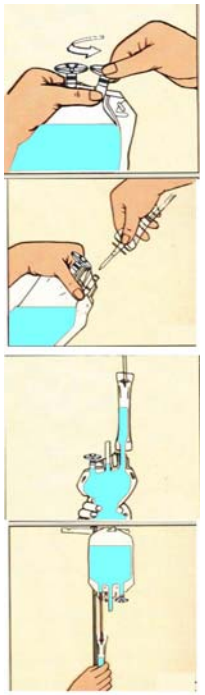

Figure1

GENERAL PRECAUTIONS TO BE TAKEN
During Storage and Transport;
- During shipment, up to two blood bags shippers shall be carried at the same time manually or on a trolley. Parcels should not be dropped and/or crushed and should be loaded in a way to prevent fall over.
- In the warehouse, up to seven parcels can be stored on top of each other and in a way to prevent fall over.

Before opening the overwrap;
- Store the solution bags in overwraps at clean, dry and cool places.
- Do not use if there is visible sign of deterioration on the overwrap.
- Solution bags are sterile packed.

Before transfusion;
- The solution bags shall be used in accordance with the instructions for use.
- It is not suitable for direct intravenous infusion.
- Do not use if the solution is not transparent, the bag is not tough or there is visible sign of deterioration.
- Solution may show light yellow colour. This is acceptable and it does not affect the safety usage of product.
- For more information look at the apheresis device guide.
- Sterile and apyrogen- It is sterilized with steam.
- Keep away the bag and the lines from the sharp objects.
- Do not use if there is no fluid path caps or the caps are loose.
- Use transfusion set compatible with ISO EN 1135-4.

After Use
- Single use. It should be thrown in medical waste box. Warning: In case of reuse, there is infection risk.

ATTENTION: This medical device contains di(2-ethylhexyl) phthalate (DEHP) içerir. Based on animal data, in the specific patient groups that have the risk of adverse effect in reproductive and developmental processes, long-term exposure to DEHP should be taken to limit. These patients are male newborns, infants and kids, peripubertal boys and pregnant or breastfeeding women. However, if its benefits are more important than any health risk related to exposure to DEHP, do not avoid medical procedures. Please refer to current literature to provide an informed decision.

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