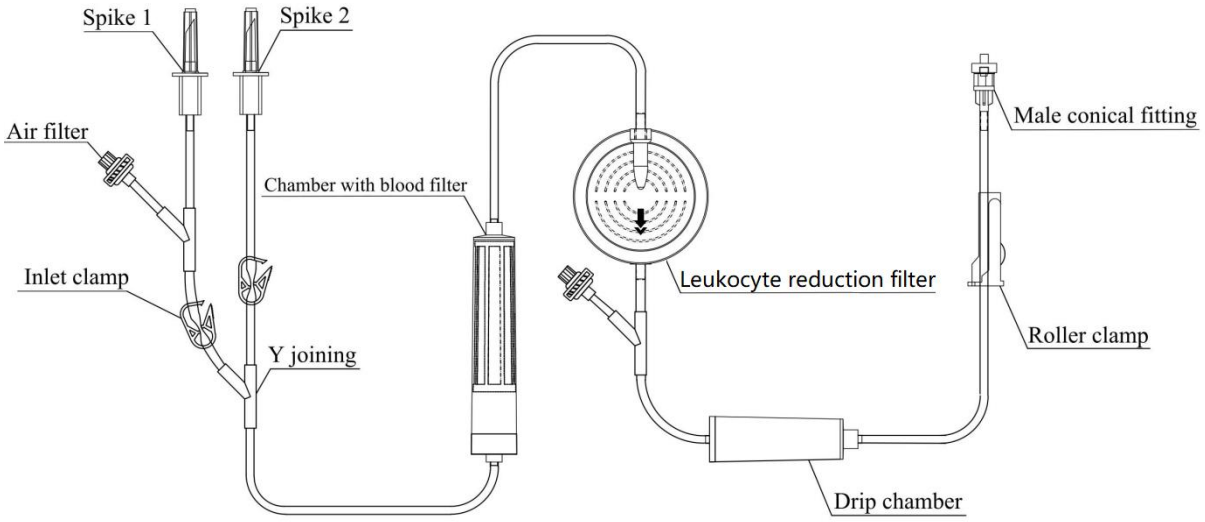
Leukocyte Reduction Filter (sets)

Instruction for Use **(FSPL01K-HE01)**

This product is used to reduce the leukocytes (white blood cells) from 5~6 units manual collection of platelet or one unit of machine collection of platelet at hospital.

Configuration



*Leukocyte Reduction Filter (FSPL01K-HE01) hereby

This product is used for bed side at hospital to process 5~6 units manual collection of platelet or one unit of machine collection of platelet at hospital.

Application and intended use

This product is used for blood transfusion at bed side in hospital, to remove the leukocytes and blood condensates from the platelets and get the leukocyte reduced blood components.

Description

- The Residual white blood cells less than 1.0 x10^6/unit and the platelet recovery rate not less than 85%.
- This filter, FSPL01K-HE01, is only for 5~6 units manual collection of platelet or one unit of machine collection of platelet.
- By filtering leukocytes and agglutinates in the blood and keep the blood usefulness, effectively prevent the virus transmission, such as leukocyte-carrying cytomegalovirus (CMV), T lymphoblastic leukemia virus (HTLV-I) and human immunodeficiency virus (HIV); prevent complication during blood transfusion, such as Non-hemolytic transfusion reactions of the febrile type (NHFR), Adult respiratory distress syndrome (ARDS), Graft-versus-host disease (GVHD) and Invalid platelet transfusion etc.

Contraindications

- None.

Warnings

- Bed side leukocyte reduction filters should not be used for pre-storage!

Precautions

- Read the instructions carefully before using, once find something wrong, such as the unit package breaking, the loosening or falling off of the protective sleeves on the spikes and the male conical fitting, the product damaged, soiled, or mouldy, please do not use!
- Dispose of safely after single use to avoid risk of infection.
- This product is disposable, for single use only. Once unpack it, please use it immediately, and destroy after use.
- Avoid direct sunlight, keep it in a condition without corrosive gas, cool, dry and less than 80%RH, well ventilated.
- The product is sterilized by ethylene oxide, warranty shelf life is 2 years.
- The product should be operated by professionals.

Instructions for use

A. Attach the Blood Unit to be Filtered

(1) Make sure to mix thoroughly shake of the platelets before filtration.
(2) Slide off the inlet clamp as close to the spike as possible. Close the inlet clamp while ensuring that the roller clamp is open.
(3) Prepare the outlet port of the blood unit to be filtered.
(4) Remove the protector from the spike on the inlet tubing and insert the spike into the outlet port of the blood unit by using a twisting motion.

B. Filter the Blood and Transfuse

(1) Hang the blood unit on an I.V.stand at a height of approximately 1 meter.
(2) Connect the male conical fitting with blood transfusion needle, and insert the venipuncture site in the patient's arm, open the inlet clamp, adjust the speed.
(3) Start transfusing.
(4) When the blood unit and the inlet tubing has emptied, close all clamps and remove the transfusion set.

Note: （1）The filtrations performed at ambient temperatures shall be completed within eight hours.
（2）The filter has been designed and validated to meet the criteria of a leukoreduction filter for bedside type. The filter's performance must be validated using your facility's standard operating procedure (SOP) on component preparation and handling.
Any filtration that fails to meet the filtration specifications established by the facility's validation should be evaluated for residual leukocytes and red blood cell (RBC) recovery after filtration. Note that unusual attributes such as sickle cell trait, excessive blood clotting and gel formation, and poor mixing during collection and processing of components can contribute to the failure of a filtration to meet filtration specifications

Caution

- DAJI MEDICAL FILTER cannot be reprocessed or reused. It is intended for single use only.
- Dispose of the used DAJI MEDICAL FILTER in strict accordance with official and institution standards for medical waste disposal.
- Do not use DAJI MEDICAL FILTER for any purpose other than leukocyte removal.
- Do not use if DAJI MEDICAL FILTER is damaged or if sterile bag is not properly sealed.
- To avoid contamination, do not remove DAJI MEDICAL FILTER from sterile bag until ready for use.
- Proper aseptic techniques must be used when handling with DAJI MEDICAL FILTER.
- Carefully read this instruction sheet for proper use of DAJI MEDICAL FILTER.
- Store DAJI MEDICAL FILTER in a clean place. Keep away from direct sunlight, water and humidity.
- Keep DAJI MEDICAL FILTER, a plastic product, away from vibration and impact during transportation and operation

Environment requirement

For operation: Temperature: not specified, Humidity: 0%RH~80%RH

For storage: Temperature: not specified, Humidity: 0%RH~80%RH

Always dispose or recycle the worn-out products according to your local rules and regulations

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PICTOGRAMS TRANSLATION TABLE

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SYMBOL	ENGLISH	SYMBOL	ENGLISH
	Red blood cell container		Leucocyte filtration
	Do not vent		Do not use if there is visible sign of deterioration
STERILE EO	Sterilized using ethylene oxide		pcs per package
	Non-pyrogenic fluid path		Do not use if package is damaged
	Do not re-use	LATEX	Free of natural rubber latex
PHT DEHP	Contains or presence of DEHP	10 days	Contents of pack must be used within 10 days of opening
	Read instructions for use		Caution, read accompanying documents
	Use by date		Manufacturer
	Keep away from sunlight		Keep dry
6	Stacking limit by number "6"		