

Leukocyte Reduction Filter for Red Blood

PS

For Use with One Unit of Red Blood Cell product

Indication:

The Leukocyte Reduction Filter for CPDA-1 Red Blood Cells is indicated for the leukoreduction of a single unit of CPDA-1 Red Blood Cells collected from a blood donor and filtered within 8 hours when the red cells are stored at ambient temperature (20 to 24 °C), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6°C.

Device Description:

- Set length : 2,100mm (82.68 inch)
- Tube Diameter : ID 3.0mm/OD 4.1mm
- Drip chamber volume : 4 drops/mL
- Priming volume : 35mL
- Sterile : Ethylene oxide(EtO), nontoxic and non-pyrogenic fluid path
- The product is assembled at the factory

Directions for Use:

- Use the filter immediately when the protective cap is removed
- Hang up to 150cm during filtration
- The used set should be regarded as biomedical and healthcare waste and discarded in the appropriate place

Precautions:

- For optimal results leukoreduction should be performed within 72 hours after collection of the Red Blood Cells stored refrigerated at 1 to 6°C
- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- Contains or presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP)
- The use of an FDA-approved sterile connection device is required for setup when a closed system is desired
- The filtered red cell product must be properly identified per standard procedures
- Caution: Federal law restricts this device to sale by or on the order of a physician

Warning:

- Do not connect with the pressurized system
- The application of manual or mechanical force should not be used to increase the flow through the filter
- The use of a coupler or failure to maintain a closed system will require transfusing the product within 24 hours

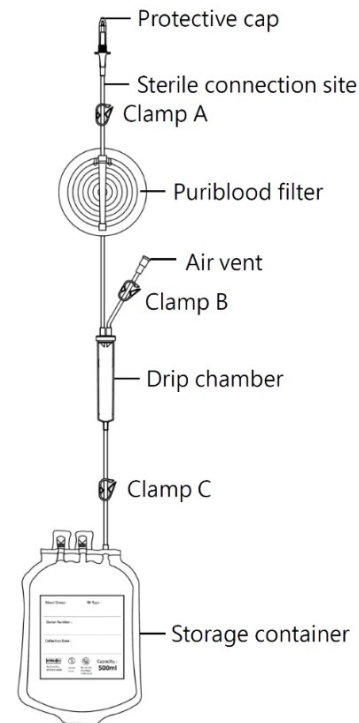
INSTRUCTION FOR USE:

Method 1. Open System Processing

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B and C completely.
3. Remove the protective cap and insert the spike into the red cell unit.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and C to start gravity infusion.
6. When the blood flow stops and the clamp B to the air vent is opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Method 2. Closed System Processing

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B and C completely.
3. To seal the storage container sterilely, connect the sterile connection site to blood bag tubing.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and C to start gravity infusion.
6. When the blood flow stops and the clamp B to the air vent is opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.



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MedNet GmbH
Borkstrasse 10 48163 Muenster Germany

Manufactured for: PURIBLOOD MEDICAL CO., LTD.
2F, No.11, Gongye E. 9th Rd., Baoshan Township, Hsinchu County 30075, Taiwan (R.O.C.)

By: Innovative Medical Manufacturing Company
No.107, LN. 181, Sec. 1, Yongzhen Rd., Zhunan Township, Miaoli County 35057, Taiwan (R.O.C.)

Leukocyte Reduction Filter for Red Blood

For Use with One Unit of Red Blood Cell product

PS

Indication:

The Leukocyte Reduction Filter for CPDA-1 Red Blood Cells is indicated for the leukoreduction of a single unit of CPDA-1 Red Blood Cells collected from a blood donor and filtered within 8 hours when the red cells are stored at ambient temperature (20 to 24 °C), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6°C.

Device Description:

- Set length : 2,100mm (82.68 inch)
- Tube Diameter : ID 3.0mm/OD 4.1mm
- Drip chamber volume : 4 drops/mL
- Priming volume : 35mL
- Sterile : Ethylene oxide(EtO), nontoxic and non-pyrogenic fluid path
- The product is assembled at the factory

Directions for Use:

- Use the filter immediately when the protective cap is removed
- Hang up to 150cm during filtration
- The used set should be regarded as biomedical and healthcare waste and discarded in the appropriate place

INSTRUCTION FOR USE:

Method 1. Open System Processing

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C and D completely.
3. Remove the protective cap and insert the spike into the red cell unit.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and D to start gravity infusion.
6. When the blood flow stops and the clamp B and C to the air vent are opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Method 2. Closed System Processing

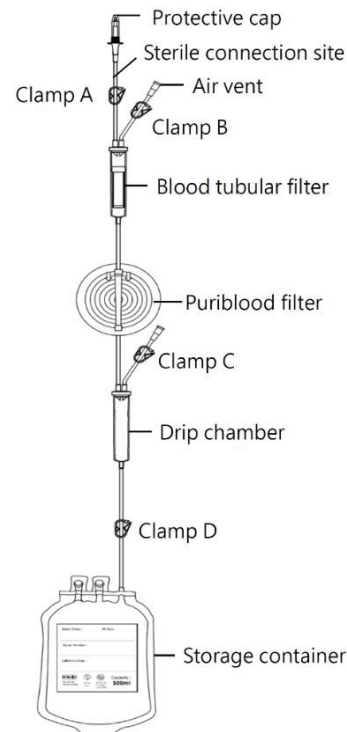
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C and D completely.
3. To seal the storage container sterily, connect the sterile connection site tubing on the filter set to blood bag tubing
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and D to start gravity transfusion.
6. When the blood flow stops and the clamp B and C to the air vent are opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Precautions:

- For optimal results leukoreduction should be performed within 72 hours after collection of the Red Blood Cells stored refrigerated at 1 to 6°C
- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- Contains or presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP)
- The use of an FDA-approved sterile connection device is required for setup when a closed system is desired
- The filtered red cell product must be properly identified per standard procedures
- Caution: Federal law restricts this device to sale by or on the order of a physician

Warning:

- Do not connect with the pressurized system
- The application of manual or mechanical force should not be used to increase the flow through the filter
- The use of a coupler or failure to maintain a closed system will require transfusing the product within 24 hours



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Leukocyte Reduction Filter for Red Blood

For Use with One Unit of Red Blood Cell product

PS

Indication:

The Leukocyte Reduction Filter for CPDA-1 Red Blood Cells is indicated for the leukoreduction of a single unit of CPDA-1 Red Blood Cells collected from a blood donor and filtered within 8 hours when the red cells are stored at ambient temperature (20 to 24 °C), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6°C.

Device Description:

- Set length : 2,200mm (86.61 inch)
- Tube Diameter : ID 3.0mm/OD 4.1mm
- Drip chamber volume : 4 drops/mL
- Priming volume : 35mL
- Sterile : Ethylene oxide(EtO), nontoxic and non-pyrogenic fluid path
- The product is assembled at the factory

Directions for Use:

- Use the filter immediately when the protective cap is removed
- Hang up to 150cm during filtration
- The used set should be regarded as biomedical and healthcare waste and discarded in the appropriate place

INSTRUCTION FOR USE:

Method 1. Open System Processing

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C and D completely.
3. Remove the protective cap, insert spike A into the red cell unit and insert spike B into the saline bag if needed.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and D to start gravity infusion.
6. When the blood flow stops and the clamp C to the air vent is opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Method 2. Closed System Processing

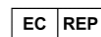
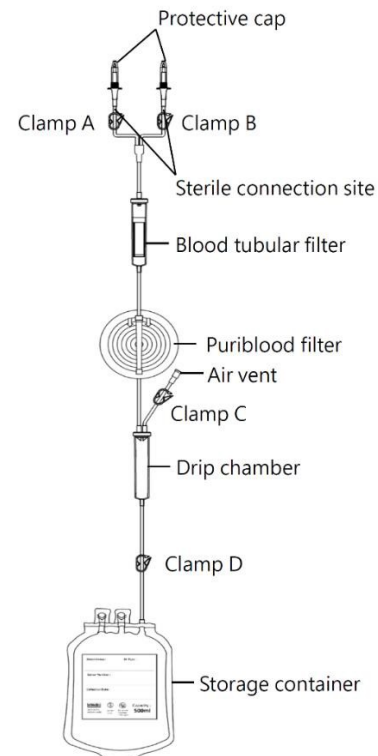
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C and D completely.
3. To seal the storage container sterilely, connect the sterile connection site tubing to the filter set with the red cell unit at Spike A, and with the saline bag at Spike B.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and D to start gravity transfusion.
6. When the blood flow stops and the clamp C to the air vent is opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Precautions:

- For optimal results leukoreduction should be performed within 72 hours after collection of the Red Blood Cells stored refrigerated at 1 to 6°C
- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- Contains or presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP)
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Indication:

The Leukocyte Reduction Filter for CPDA-1 Red Blood Cells is indicated for the leukoreduction of a single unit of CPDA-1 Red Blood Cells collected from a blood donor and filtered within 8 hours when the red cells are stored at ambient temperature (20 to 24 °C), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6°C.

Device Description:

- Set length : 2,900mm (114.17 inch)
- Tube Diameter : ID 3.0mm/OD 4.1mm
- Drip chamber volume : 4 drops/mL
- Priming volume : 35mL
- Sterile : Ethylene oxide(EtO), nontoxic and non-pyrogenic fluid path
- The product is assembled at the factory

Directions for Use:

- Use the filter immediately when the protective cap is removed
- Hang up to 150cm during filtration
- The used set should be regarded as biomedical and healthcare waste and discarded in the appropriate place

INSTRUCTION FOR USE:

Method 1. Open System Processing

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C, D and the roller clamp completely.
3. Remove the protective cap, insert spike A into the red cell unit and insert spike B into the saline bag if needed.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and the roller clamp to start gravity transfusion.
6. When the blood flow stops and the clamp C to the air vent and D through the tubing are opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the tubing and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Method 2. Closed System Processing

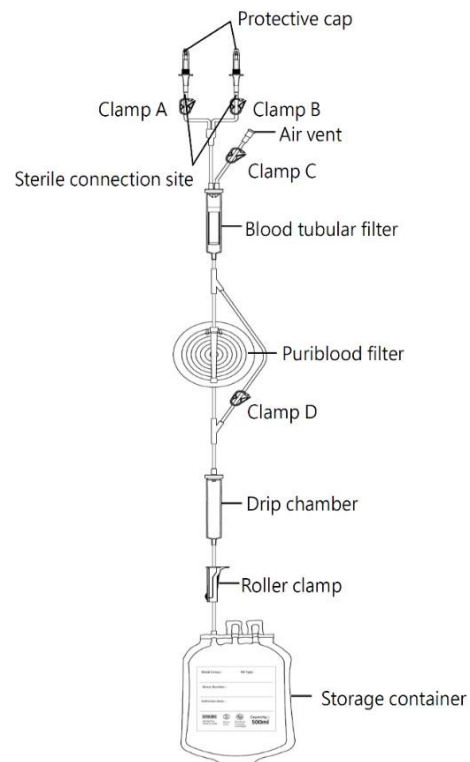
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C, D and the roller clamp completely.
3. To seal the storage container sterilely, connect the sterile connection site to the filter set with the red cell unit at Spike A, and with the saline bag at Spike B if needed.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and the roller clamp to start gravity transfusion.
6. When the blood flow stops and the clamp C to the air vent and D through the tubing are opened, the filtered red cell container is gently squeezed until the air is expelled through the air vent and the tubing and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Precautions:

- For optimal results leukoreduction should be performed within 72 hours after collection of the Red Blood Cells stored refrigerated at 1 to 6°C
- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- Contains or presence of phthalate: bis (2-ethylhexyl) phthalate(DEHP)
- The use of an FDA-approved sterile connection device is required for setup when a closed system is desired
- The filtered red cell product must be properly identified per standard procedures
- Caution:Federal law restricts this device to sale by or on the order of a physician

Warning:

- Do not connect with the pressurized system
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- The use of a coupler or failure to maintain a closed system will require transfusing the product within 24 hours



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Indication:

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Device Description:

- Set length : 2,270mm (89.37 inch)
- Tube Diameter : ID 3.0mm/OD 4.1mm
- Drip chamber volume : 4 drops/mL
- Priming volume : 35mL
- Sterile : Ethylene oxide(ETO), nontoxic and non-pyrogenic fluid path
- The product is assembled at the factory

Directions for Use:

- Use the filter immediately when the protective cap is removed
- Hang up to 150cm during filtration
- The used set should be regarded as biomedical and healthcare waste and discarded in the appropriate place

INSTRUCTION FOR USE:

Method 1. Open System Processing

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A and B completely.
3. Remove the protective cap and insert the spike into the red cell unit.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A to start gravity infusion.
6. When the blood flow stops and the clamp B through the tubing is opened, the filtered red cell container is gently squeezed until the air is expelled through the tubing and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube above the storage container and store at 1-6°C.

Method 2. Closed System Processing

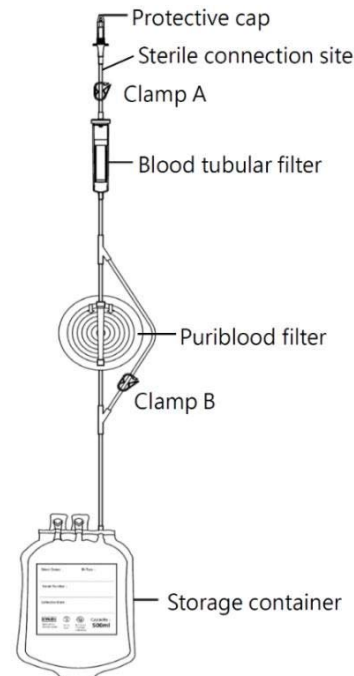
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A and B completely.
3. To seal the storage container sterile, connect the sterile connection site on the filter set to blood bag tubing.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A to start gravity infusion.
6. When the blood flow stops and the clamp B through the tubing is opened, the filtered red cell container is gently squeezed until the air is expelled through the tubing and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube below the drip chamber and store the container at 1-6°C.

Precautions:

- For optimal results leukoreduction should be performed within 72 hours after collection of the Red Blood Cells stored refrigerated at 1 to 6°C
- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- Contains or presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP)
- The use of an FDA-approved sterile connection device is required for setup when a closed system is desired
- The filtered red cell product must be properly identified per standard procedures
- Caution: Federal law restricts this device to sale by or on the order of a physician

Warning:

- Do not connect with the pressurized system
- The application of manual or mechanical force should not be used to increase the flow through the filter
- The use of a coupler or failure to maintain a closed system will require transfusing the product within 24 hours



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Leukocyte Reduction Filter for Red Blood

For Use with One Unit of Red Blood Cell product

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Indication:

The Leukocyte Reduction Filter for CPDA-1 Red Blood Cells is indicated for the leukoreduction of a single unit of CPDA-1 Red Blood Cells collected from a blood donor and filtered within 8 hours when the red cells are stored at ambient temperature (20 to 24 °C), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6°C.

Device Description:

- Set length : 1,830mm (72.05 inch)
- Tube Diameter : ID 3.0mm/OD 4.1mm
- Drip chamber volume : 4 drops/mL
- Priming volume : 35mL
- Sterile : Ethylene oxide(ETO), nontoxic and non-pyrogenic fluid path
- The product is assembled at the factory

Directions for Use:

- Use the filter immediately when the protective cap is removed
- Hang up to 150cm during filtration
- The used set should be regarded as biomedical and healthcare waste and discarded in the appropriate place

INSTRUCTION FOR USE:

Method 1. Open System Processing

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A and B completely.
3. Remove the protective cap and insert the spike into the red cell unit.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A to start gravity infusion.
6. When the blood flow stops and the clamp B through the tubing is opened, the filtered red cell container is gently squeezed until the air is expelled through the tubing and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube above the storage container and store at 1-6°C.

Method 2. Closed System Processing

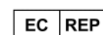
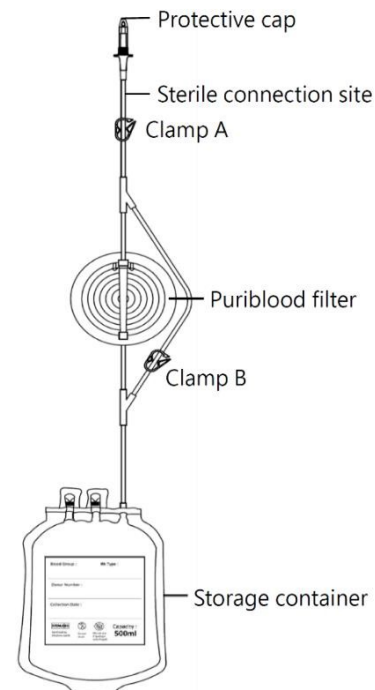
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A and B completely.
3. To seal the storage container sterilely, connect the sterile connection site on the filter set to blood bag tubing.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A to start gravity infusion.
6. When the blood flow stops and the clamp B through the tubing is opened, the filtered red cell container is gently squeezed until the air is expelled through the tubing and the filtered blood fills the donor segment tubing as desired.
7. After all the processes, to close all the clamps and seal the tube above the storage container and store at 1-6°C.

Precautions:

- For optimal results leukoreduction should be performed within 72 hours after collection of the Red Blood Cells stored refrigerated at 1 to 6°C
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