

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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 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

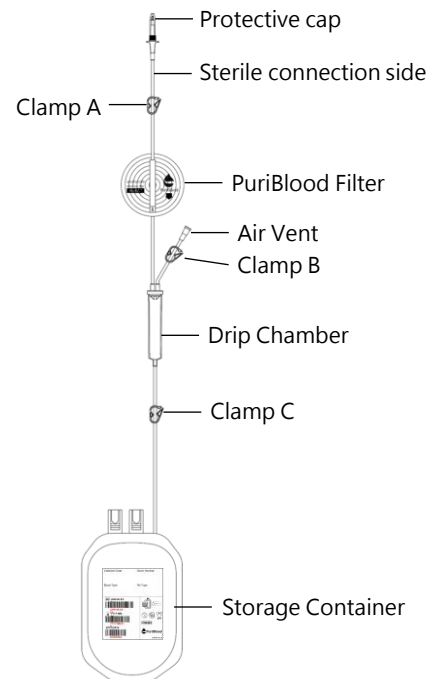
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B and C completely.
3. To seal the storage container sterilely, connect the sterile connection site tubing on the filter set to blood bag tubing.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and 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.

## Precautions:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations.
- 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.



MedNet EC-REP 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.)

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 :1,810mm (71.26 inch)
- Tube Diameter : ID 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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:

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Open the package, and close Clamp A, B, C and the roller clamp 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, C and the roller clamp, completely fill the blood into the system, and make sure the drip chamber to be half-full of blood.
6. Close Clamp C and the roller clamp.
7. Remove the protective cap from the luer-lock adapter, connect the luer-lock adapter to the infusion needle to perform venipuncture, and adjust the flow by the roller clamp.
8. When the blood bag is empty, open Clamp B to speed up the filtration of residual blood if the filtering speed is slow.
9. Once the transfusion is finished, close the roller clamp and seal the tube below the drip chamber before removing the set.

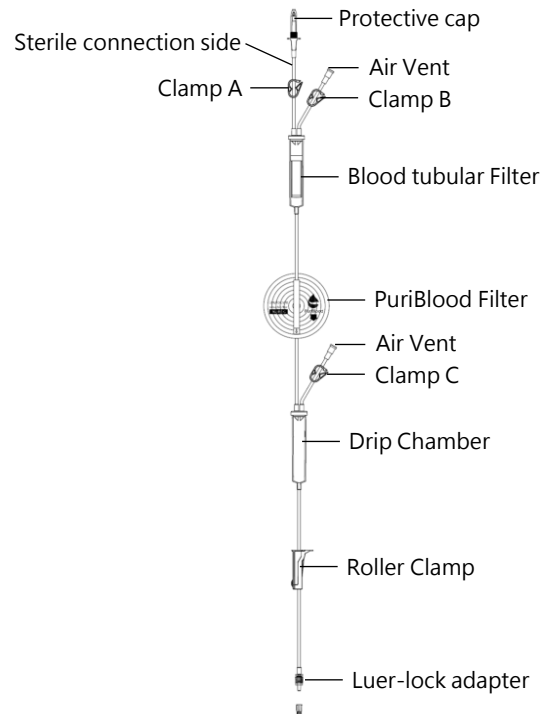
Warning: This procedure should be practiced by trained operators in case of infusing air into the system.

## Precautions:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations
- 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.
- When using the bedside system, make sure the blood in the filter set is fully filled before connecting to the patient to avoid causing harm to the patient.



MedNet EC-REP 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.)

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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:

1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Open the package, and close Clamp A, B, C 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, C and the roller clamp, completely fill the blood into the system, and make sure the drip chamber to be half-full of blood.
6. Close Clamp C and the roller clamp.
7. Remove the protective cap from the luer-lock adapter, connect the luer-lock adapter to the infusion needle to perform venipuncture, and adjust the flow by the roller clamp.
8. When the blood bag is empty, open Clamp C to speed up the filtration of residual blood if the filtering speed is slow.
9. Once the transfusion is finished, close the roller clamp and seal the tube below the drip chamber before removing the set.

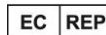
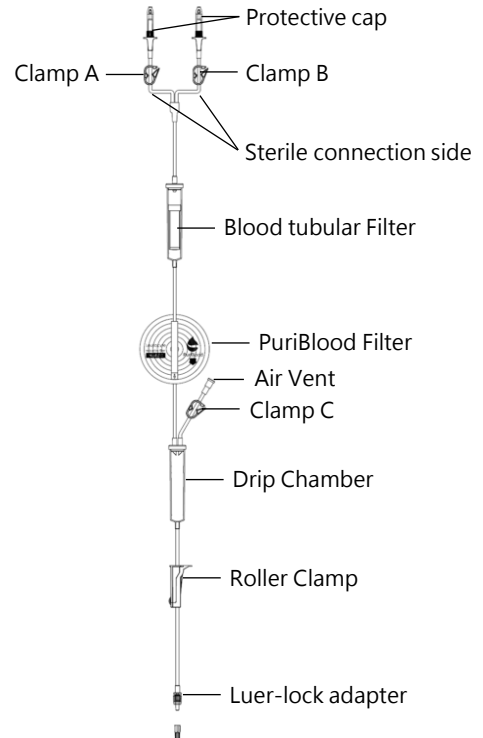
Warning: This procedure should be practiced by trained operators in case of infusing air into the system.

## Precautions:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations
- 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.
- When using the bedside system, make sure the blood in the filter set is fully filled before connecting to the patient to avoid causing harm to the patient.



MedNet EC-REP 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.)

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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

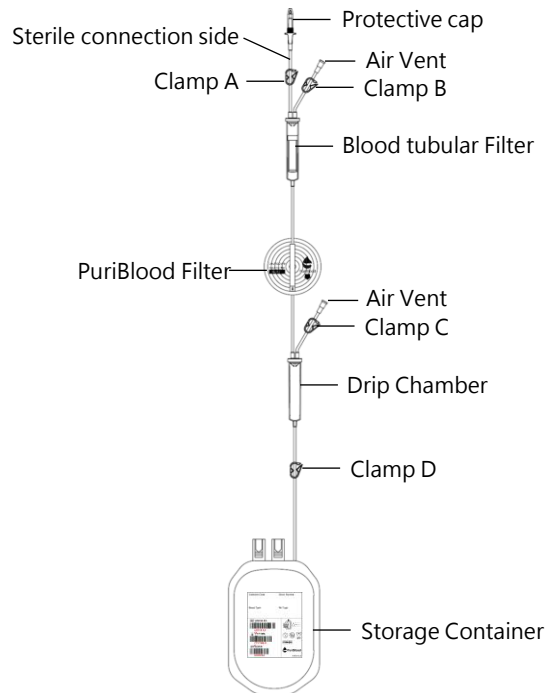
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C and D completely.
3. To seal the storage container sterilely, connect the sterile connection site tubing on the filter set to blood bag tubing
4. Hang the red cell 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:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations.
- 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.



MedNet EC-REP 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.)

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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

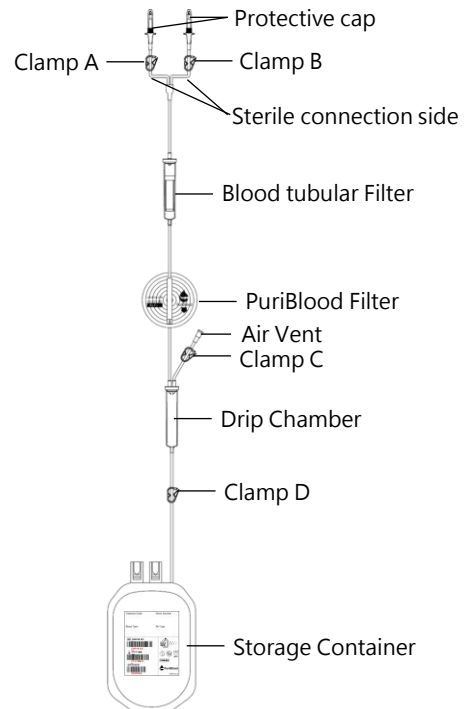
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C and D completely.
3. To seal the storage container sterilely, connect the sterile connection site tubing to the filter set with the red cell unit at Spike A, and 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:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations.
- 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.



MedNet EC-REP 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.)

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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

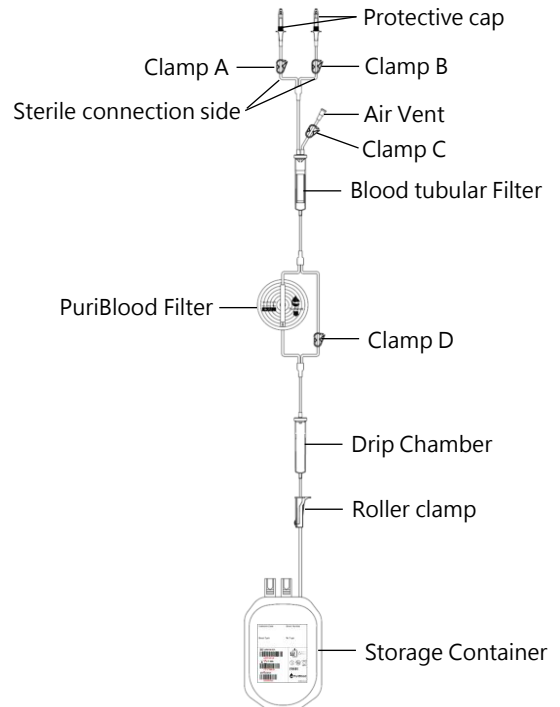
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C, D and the roller clamp completely.
3. To seal the storage container sterile, connect the sterile connection site to the filter set with the red cell unit at Spike 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:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations
- 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.



MedNet EC-REP 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.)

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 : 2,270mm (89.37 inch)
- Tube Diameter : ID 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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 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 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

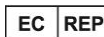
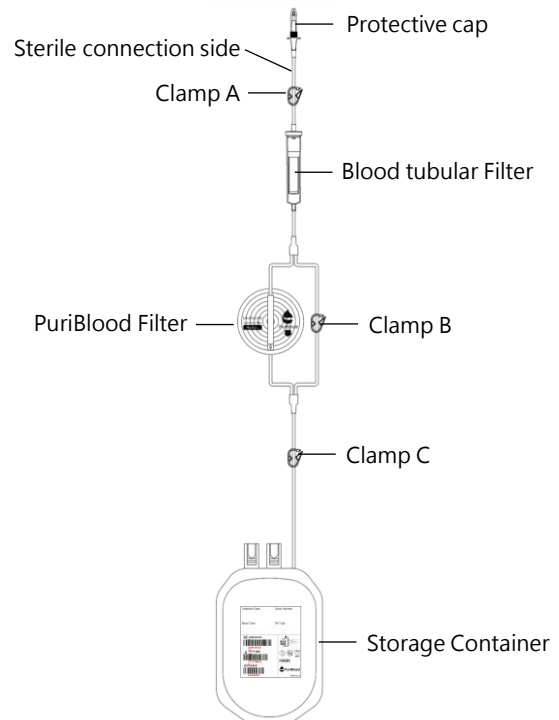
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B and C completely.
3. To seal the storage container sterilely, connect the sterile connection site on the filter set to blood bag tubing.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and C 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:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations
- 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.



MedNet EC-REP 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.)

# “Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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 healthy adult 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 2.8mm/OD 4.1mm
- Drip chamber volume : 20 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:

- Single use only; do not re-sterilize or reuse
- Do not use if package is damaged
- This product may dissolve the plasticizer Di(2-ethylhexyl)phthalate (DEHP). When used by sensitive groups such as male infants, pregnant or lactating women, and adolescent males, medical professionals are advised to include DEHP's health risk concerns into clinical treatment considerations
- 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

## INSTRUCTION FOR USE:

### Method 1. Open System Processing

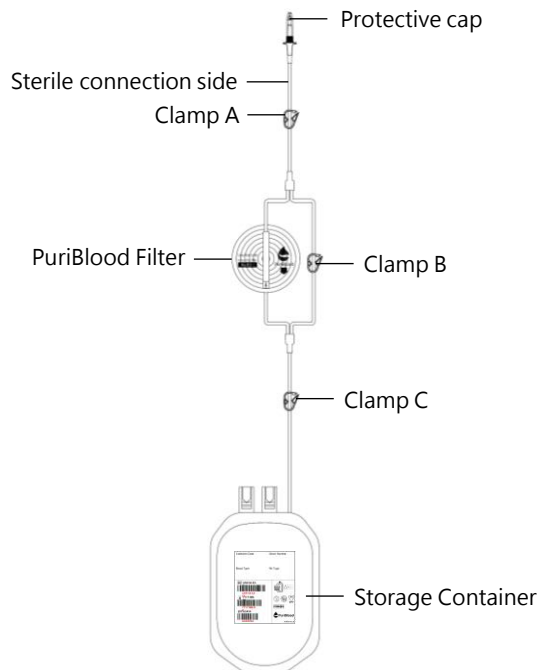
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B and C completely.
3. Remove the protective cap and insert the spike into the red cell unit.
4. Hang the red cell unit on I.V. pole or hook it to remain vertical.
5. Open Clamp A and C to start gravity infusion.
6. When the blood flow stops and the clamp B 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, B and C 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 and C 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.

## 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
- If the packaging is broken or the product is not immediately used after unsealing, it may cause pollution, product contamination may cause harm to blood transfusion patients.



MedNet EC-REP 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.)