“Puriblood” Leukocyte Reduction Filter for Red Blood Cells

For Use with One Unit of Red Blood Cell product

Intended use

Remove leukocytes from the packed red blood cells.

Introduction

Pre-storage leukocyte reduction involves using a specialized blood separation machine to collect leukocyte-reduced blood products, or the removal of white blood cells is completed as soon as possible after blood collection, before storage.

Bedside leukocyte reduction refers to the process performed at the patient's bedside, where a leukocyte filter is used to remove white blood cells from the blood bag during transfusion.

Intended patient population and indications

1. The patient has experienced non-hemolytic febrile transfusion reactions more than twice due to blood transfusions.
2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

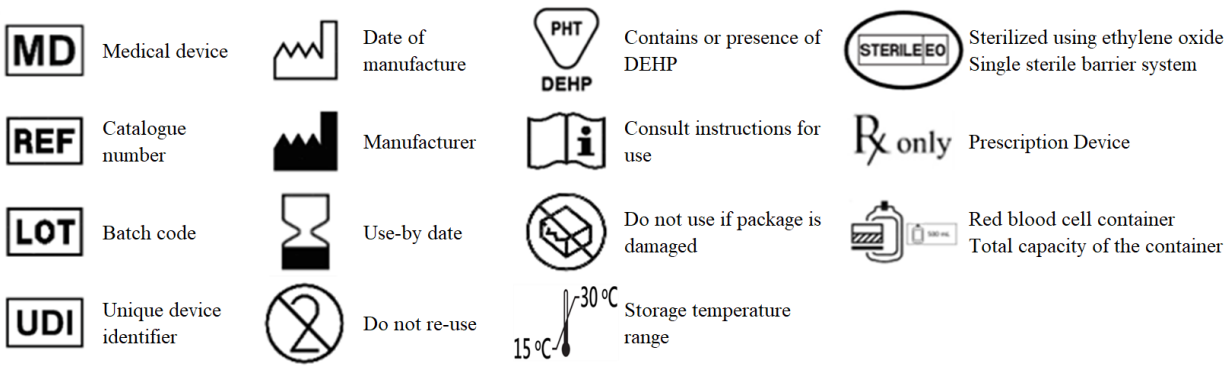
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-01-PS

“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 ℃), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6 ℃. Filtration should be conducted at room temperature. After filtration, the transfer bag containing the red blood cells should be stored at 2 to 6 ℃.

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℃.

Method 2. Closed System Processing

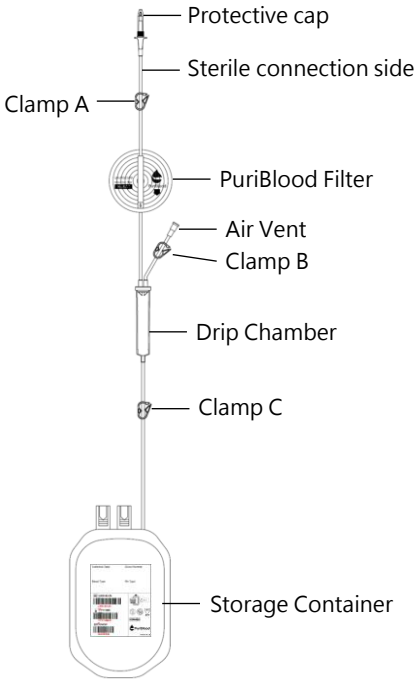
1. Beforeconnection site tubing on the filter set to blood bag tubing. filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B and C completely.
3. To seal the storage container sterilely, connect the sterile
   Note：Blood bag tube and spike connection tube are placed on the sterile connection machine, using high-temperature cutting than move the stage to seal two tubes into one, to reach sterility requirements.
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℃.

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.
- If any adverse events occur while using this medical device, please report it to the manufacturer and the competent authority.



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Manufactured for: PURIBLOOD MEDICAL CO., LTD.
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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

Intended use

Remove leukocytes from the packed red blood cells.

Introduction

Pre-storage leukocyte reduction involves using a specialized blood separation machine to collect leukocyte-reduced blood products, or the removal of white blood cells is completed as soon as possible after blood collection, before storage.

Bedside leukocyte reduction refers to the process performed at the patient's bedside, where a leukocyte filter is used to remove white blood cells from the blood bag during transfusion.

Intended patient population and indications

1. The patient has experienced non-hemolytic febrile transfusion reactions more than twice due to blood transfusions.
2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

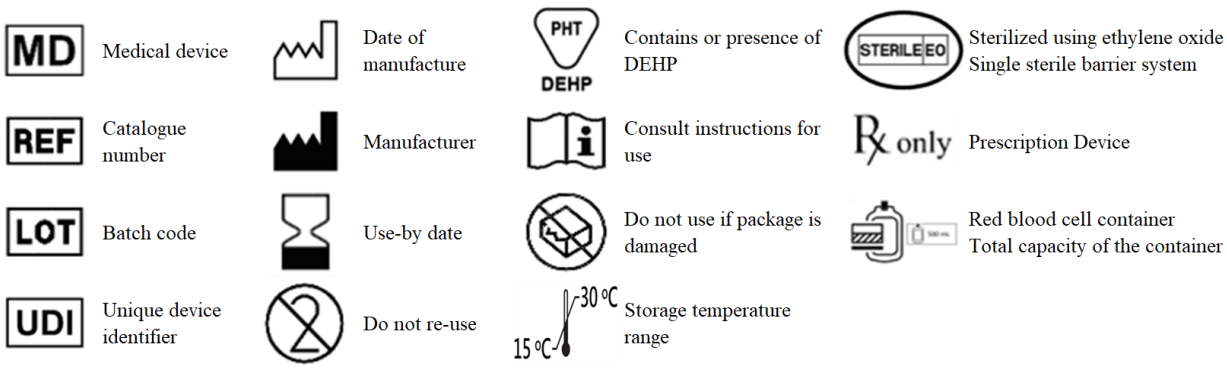
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-04-BS

“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. Filtration should be conducted at room temperature. After filtration, the transfer bag containing the red blood cells should be stored at 2 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.

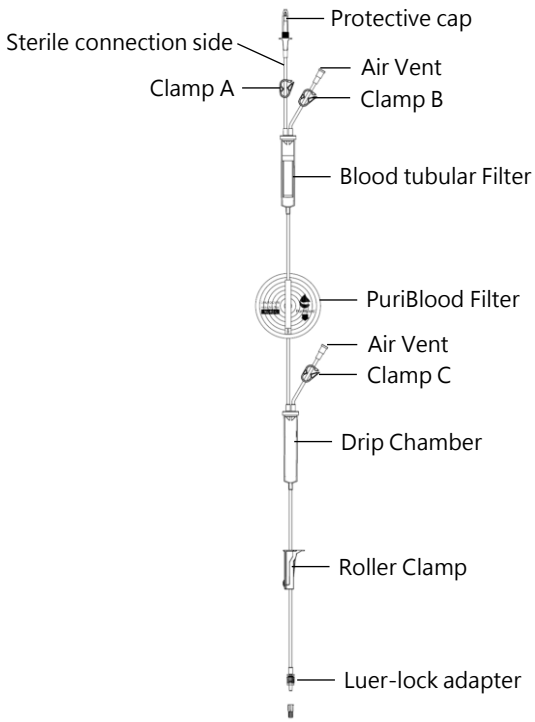
Warning: This procedure should be practiced by trained operators in case of infusing air into the system.

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.
- If any adverse events occur while using this medical device, please report it to the manufacturer and the competent authority.



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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

Intended use

Remove leukocytes from the packed red blood cells.

Introduction

Pre-storage leukocyte reduction involves using a specialized blood separation machine to collect leukocyte-reduced blood products, or the removal of white blood cells is completed as soon as possible after blood collection, before storage.

Bedside leukocyte reduction refers to the process performed at the patient's bedside, where a leukocyte filter is used to remove white blood cells from the blood bag during transfusion.

Intended patient population and indications

1. The patient has experienced non-hemolytic febrile transfusion reactions more than twice due to blood transfusions.
2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

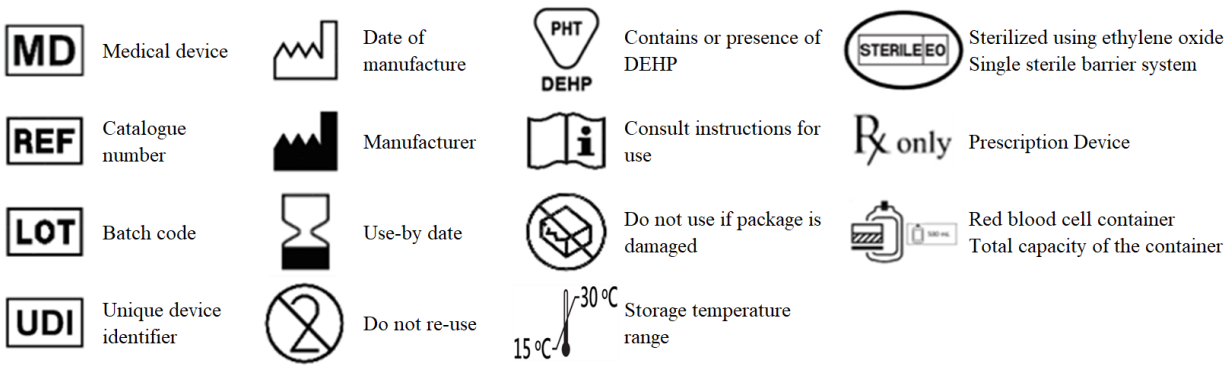
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-05-BS

“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. Filtration should be conducted at room temperature. After filtration, the transfer bag containing the red blood cells should be stored at 2 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.

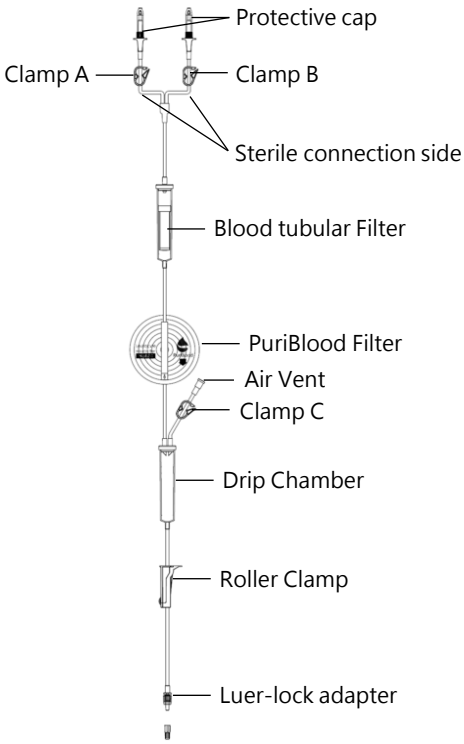
Warning: This procedure should be practiced by trained operators in case of infusing air into the system.

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.
- If any adverse events occur while using this medical device, please report it to the manufacturer and the competent authority.



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普瑞博生技 PuriBlood

MD LRW-50-04-PS

“Puriblood” Leukocyte Reduction Filter for Red Blood Cells

For Use with One Unit of Red Blood Cell product

Intended use

Remove leukocytes from the packed red blood cells.

Introduction

Pre-storage leukocyte reduction involves using a specialized blood separation machine to collect leukocyte-reduced blood products, or the removal of white blood cells is completed as soon as possible after blood collection, before storage.

Bedside leukocyte reduction refers to the process performed at the patient's bedside, where a leukocyte filter is used to remove white blood cells from the blood bag during transfusion.

Intended patient population and indications

1. The patient has experienced non-hemolytic febrile transfusion reactions more than twice due to blood transfusions.
2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

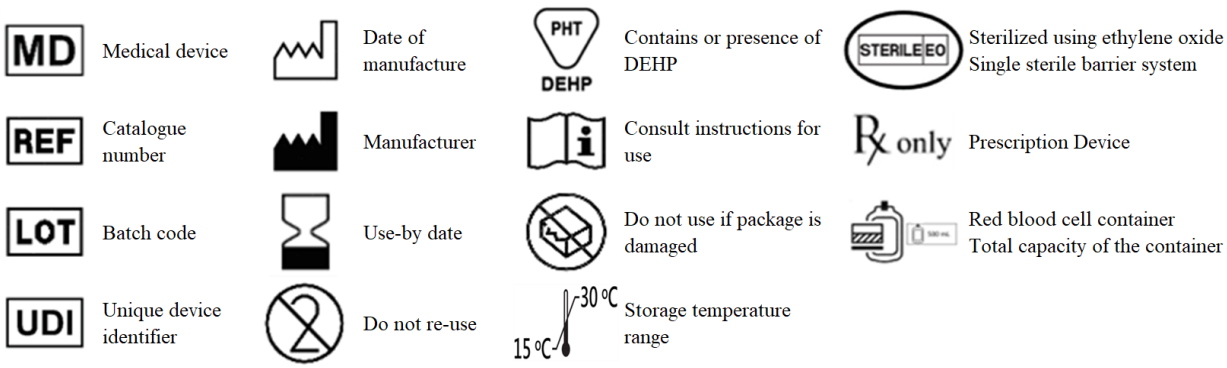
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-04-PS

“Puriblood” Leukocyte Reduction Filter for Red Blood Cells

For Use with One Unit of Red Blood Cell product

Indication:

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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℃.

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
   Note：Blood bag tube and spike connection tube are placed on the sterile connection machine, using high-temperature cutting than move the stage to seal two tubes into one, to reach sterility requirements.
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℃.

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
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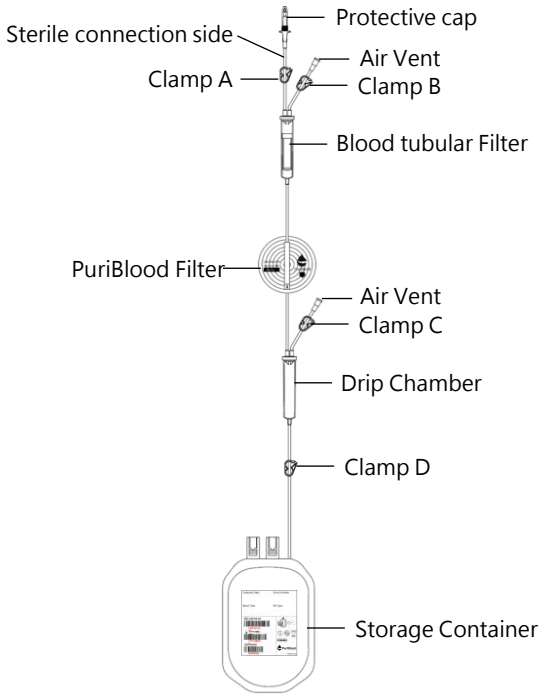

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“Puriblood” Leukocyte Reduction Filter for Red Blood Cells

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Intended use

Remove leukocytes from the packed red blood cells.

Introduction

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Intended patient population and indications

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2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

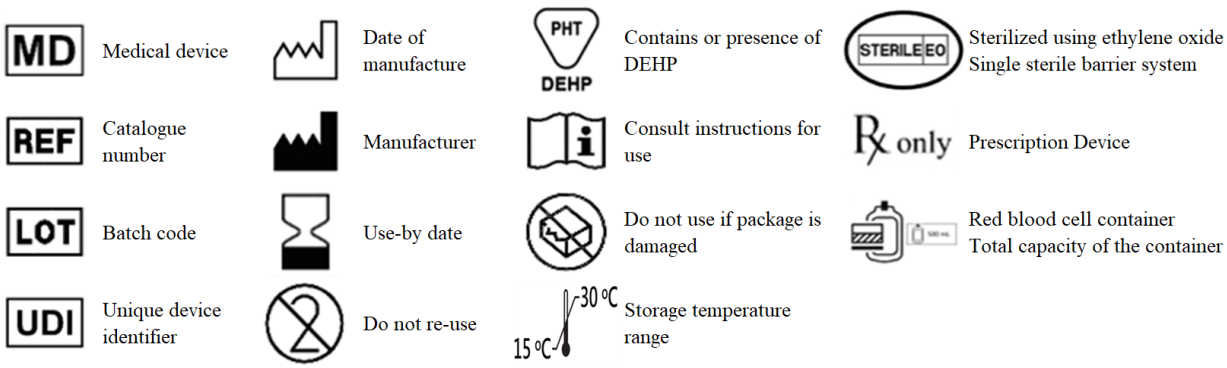
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-05-PS

“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 ℃), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6 ℃. Filtration should be conducted at room temperature. After filtration, the transfer bag containing the red blood cells should be stored at 2 to 6 ℃.

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℃.

Method 2. Closed System Processing

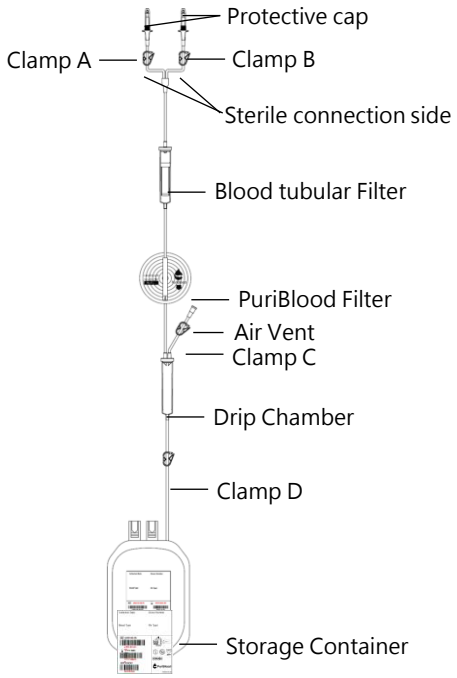
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C and D completely.
3. To seal the storage container sterilely, connect the sterile connection site tubing to the filter set with the red cell unit at Spike A, and with the saline bag at Spike B.
   Note：Blood bag tube and spike connection tube are placed on the sterile connection machine, using high-temperature cutting than move the stage to seal two tubes into one, to reach sterility requirements.
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℃.

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.
- If any adverse events occur while using this medical device, please report it to the manufacturer and the competent authority.



CE 2797 EU REP MedNet EC-REP IIb GmbH
Borkstrasse 10 48163 Münster Germany

Manufactured for: PURIBLOOD MEDICAL CO., LTD.
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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

Intended use

Remove leukocytes from the packed red blood cells.

Introduction

Pre-storage leukocyte reduction involves using a specialized blood separation machine to collect leukocyte-reduced blood products, or the removal of white blood cells is completed as soon as possible after blood collection, before storage.

Bedside leukocyte reduction refers to the process performed at the patient's bedside, where a leukocyte filter is used to remove white blood cells from the blood bag during transfusion.

Intended patient population and indications

1. The patient has experienced non-hemolytic febrile transfusion reactions more than twice due to blood transfusions.
2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

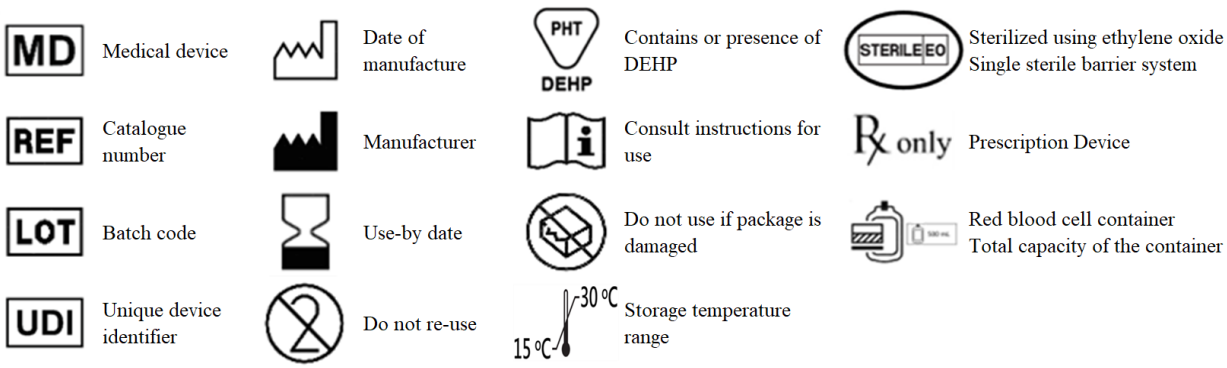
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-06-PS

“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 ℃), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6 ℃. Filtration should be conducted at room temperature. After filtration, the transfer bag containing the red blood cells should be stored at 2 to 6 ℃.

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℃.

Method 2. Closed System Processing

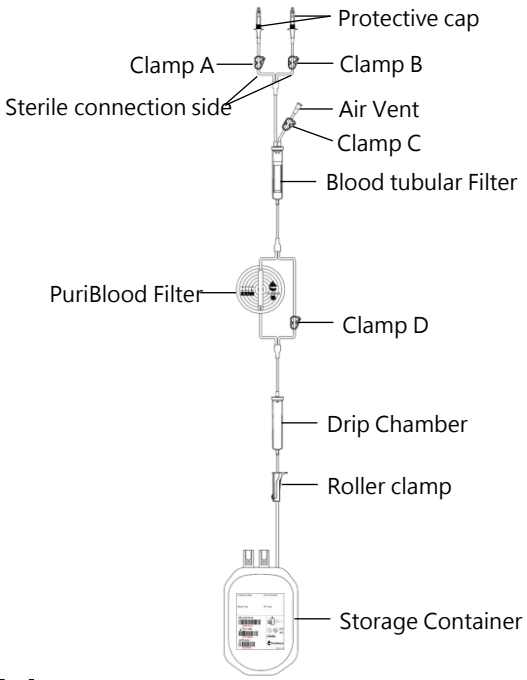
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B, C, D and the roller clamp completely.
3. To seal the storage container sterilely, connect the sterile connection site to the filter set with the red cell unit at Spike A, and with the saline bag at Spike B if needed.
   Note：Blood bag tube and spike connection tube are placed on the sterile connection machine, using high-temperature cutting than move the stage to seal two tubes into one, to reach sterility requirements.
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℃.

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.
- If any adverse events occur while using this medical device, please report it to the manufacturer and the competent authority.



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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

Intended use

Remove leukocytes from the packed red blood cells.

Introduction

Pre-storage leukocyte reduction involves using a specialized blood separation machine to collect leukocyte-reduced blood products, or the removal of white blood cells is completed as soon as possible after blood collection, before storage.

Bedside leukocyte reduction refers to the process performed at the patient's bedside, where a leukocyte filter is used to remove white blood cells from the blood bag during transfusion.

Intended patient population and indications

1. The patient has experienced non-hemolytic febrile transfusion reactions more than twice due to blood transfusions.
2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

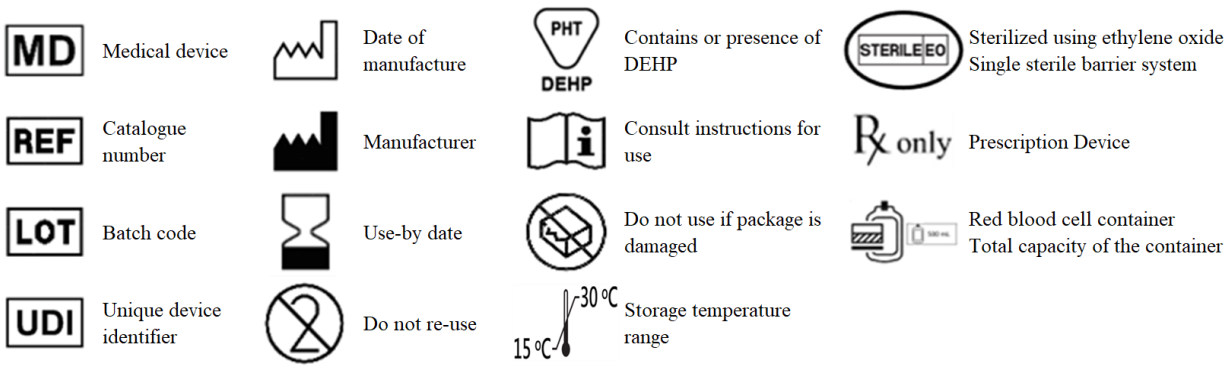
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-07-PS

“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. Filtration should be conducted at room temperature. After filtration, the transfer bag containing the red blood cells should be stored at 2 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℃.

Method 2. Closed System Processing

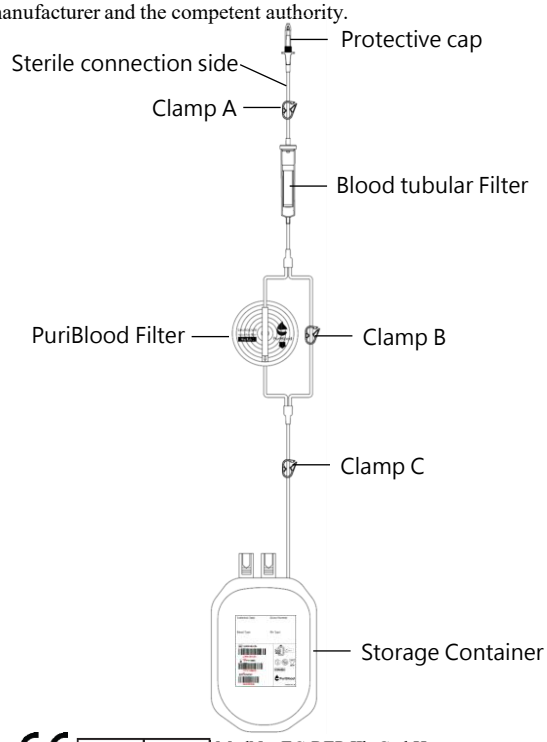
1. Before filtration, evenly and gently shake the blood bag with unfiltered red cell unit in case of stratification.
2. Close Clamp A, B and C completely.
3. To seal the storage container sterilely, connect the sterile connection site on the filter set to blood bag tubing.
   Note：Blood bag tube and spike connection tube are placed on the sterile connection machine, using high-temperature cutting than move the stage to seal two tubes into one, to reach sterility requirements.
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℃.

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.
- If any adverse events occur while using this medical device, please report it to the manufacturer and the competent authority.



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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

Intended use

Remove leukocytes from the packed red blood cells.

Introduction

Pre-storage leukocyte reduction involves using a specialized blood separation machine to collect leukocyte-reduced blood products, or the removal of white blood cells is completed as soon as possible after blood collection, before storage.

Bedside leukocyte reduction refers to the process performed at the patient's bedside, where a leukocyte filter is used to remove white blood cells from the blood bag during transfusion.

Intended patient population and indications

1. The patient has experienced non-hemolytic febrile transfusion reactions more than twice due to blood transfusions.
2. The patient requires long-term platelet transfusions.
3. The patient has plans to undergo organ transplantation.
4. Patients who require blood transfusion to avoid or delay the production of HLA antibodies.
5. Avoid CMV infection caused by blood transfusion.

Clinical benefit

In order to prevent blood transfusion infectious diseases, reduce blood transfusion reactions, enhance patient welfare, and improve blood quality, universal leukocyte depletion (ULR) measures are gradually implemented before comprehensive storage of blood products.

Environment of use

Hospital and blood bank.

Intended population

The person has expertise training such as physician, nurse and medical technologist.

Contraindications

For bedside type: When patients are receiving treatment with angiotensin-converting enzyme (ACE) inhibitors, it is recommended to avoid using this product (Model: LRW-50-04-BS, LRW-50-05-BS) for filtration steps at the bedside, as it may increase the risk of the patient being exposed to hypotensive reactions.

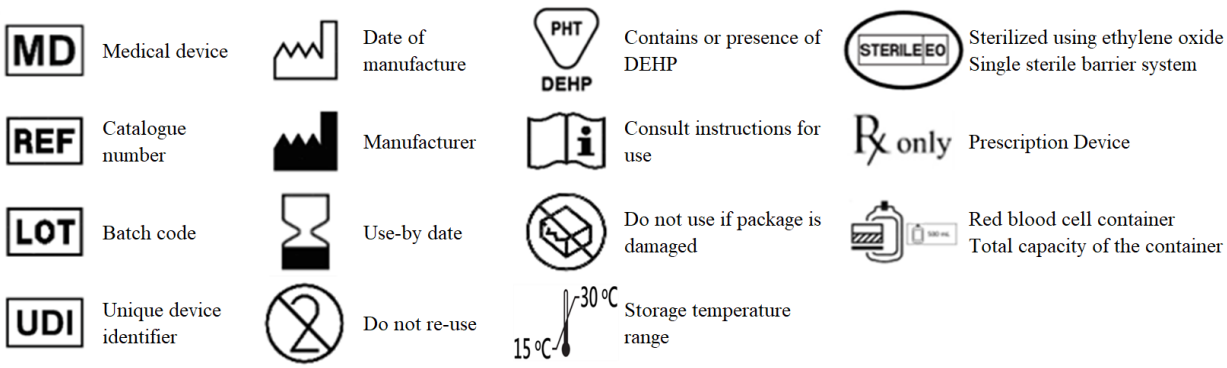
For pre-storage whitening type: Currently, no contraindications have been identified. The U.S. Food and Drug Administration (FDA) guidelines also recommend prioritizing the use of "Pre-storage White Reduction Blood Products" over those "prepared at the bedside" by hospitals.

Interaction with patient / Anatomical location of use

The proposed device will not contact with the patient directly. It only pretreatment the red blood cell before administering to the patient's vascular system.

Interaction with other devices

The proposed device will connect with blood container such as blood bag or needle.



普瑞博生技 PuriBlood

MD LRW-50-08-PS

“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. Filtration should be conducted at room temperature. After filtration, the transfer bag containing the red blood cells should be stored at 2 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:

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.
   Note：Blood bag tube and spike connection tube are placed on the sterile connection machine, using high-temperature cutting than move the stage to seal two tubes into one, to reach sterility requirements.
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.

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
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- 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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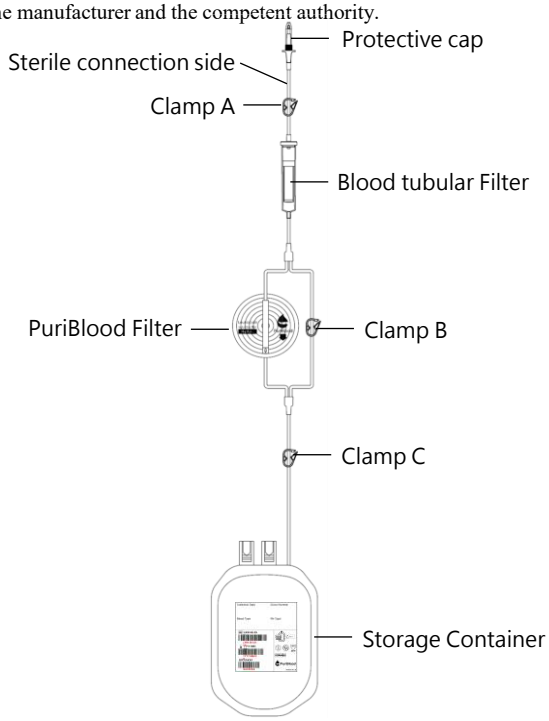

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