



Changzhou Holinx Industries Co., Ltd.

Add.: No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China

<https://www.holinx.com/>

TECHNICAL DATASHEET OF STERILE VENTED BLOOD TRANSFUSION SET WITH NEEDLE FOR SINGLE USE



PRODUCT DETAILS													
Description:	Disposable Vented Blood Transfusion Set, 155 cm, with needle 18GX1½"												
Type:	Luer Slip												
Drop Factor:	20 drops of distilled water equivalent to 1ml \pm 0.1ml (1g \pm 0.1g)												
Shelf life:	5 years from date of manufacturing												
REF No:	HBVS18/112												
Composition:	<p><i>Disposable Vented Blood Transfusion Set with needle is a medical device composed of:</i></p> <table border="1"> <tr> <td>-Drip chamber;</td><td> <p>-<u>Spike</u>, which allows effortless pierce of the blood containers rubber plug;</p> <p>-<u>Air vent</u> - is integrated above the drip chamber, allows adequate pressure inside the chamber for smooth, uninterrupted fluid flow;</p> <p>-Transparent flexible <u>drip chamber</u> facilitates rapid adjustment of fluid with further observation/monitoring of fluid flow;</p> <p>-<u>Solution filter</u> – is used to filter particulates (clots, small clumps of platelets and white blood cells that potentially might have been formed during collection and storage).</p> </td></tr> <tr> <td>-Tubing;</td><td>-Transparent kink resistant tubing smooth and uninterrupted fluid flow.</td></tr> <tr> <td>-Roller clamp;</td><td> <p>-Moves along the plastic tubing between the drip chamber and the latex-free injection connector site;</p> <p>-Allows a smooth adjustment of the flow rate from a very slow rate to a "wide open" flow rate with high precision.</p> </td></tr> <tr> <td>-Connector;</td><td> <p>-Latex injection connector at distal end of tubing, with self-sealing properties, allows intermittent medication;</p> <p>-Soft material allows easy puncture by needle.</p> </td></tr> <tr> <td>-Needle;</td><td> <p>-Luer Slip;</p> <p>-Provide sharp and smooth puncture.</p> </td></tr> <tr> <td>-Protective caps (for needle and spike).</td><td>-Tight closure ensures high level of safety against accidental needle stick injury or spike tip damage when handling the Blood Transfusion Set.</td></tr> </table>	-Drip chamber;	<p>-<u>Spike</u>, which allows effortless pierce of the blood containers rubber plug;</p> <p>-<u>Air vent</u> - is integrated above the drip chamber, allows adequate pressure inside the chamber for smooth, uninterrupted fluid flow;</p> <p>-Transparent flexible <u>drip chamber</u> facilitates rapid adjustment of fluid with further observation/monitoring of fluid flow;</p> <p>-<u>Solution filter</u> – is used to filter particulates (clots, small clumps of platelets and white blood cells that potentially might have been formed during collection and storage).</p>	-Tubing;	-Transparent kink resistant tubing smooth and uninterrupted fluid flow.	-Roller clamp;	<p>-Moves along the plastic tubing between the drip chamber and the latex-free injection connector site;</p> <p>-Allows a smooth adjustment of the flow rate from a very slow rate to a "wide open" flow rate with high precision.</p>	-Connector;	<p>-Latex injection connector at distal end of tubing, with self-sealing properties, allows intermittent medication;</p> <p>-Soft material allows easy puncture by needle.</p>	-Needle;	<p>-Luer Slip;</p> <p>-Provide sharp and smooth puncture.</p>	-Protective caps (for needle and spike).	-Tight closure ensures high level of safety against accidental needle stick injury or spike tip damage when handling the Blood Transfusion Set.
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Materials: PP, PVC, PE, ABS, PTFE, Rubber (Latex), Stainless Steel.

Sterilization: EO (Ethylene Oxide)

Product standards: ISO 8536.4-2010, GB/8369.1-2019, ISO 7864-2016

Certificates: CE, ISO 13485

Classification: MDD 93/42/EEC, Class IIa

Packaging: Single PE bag, 20pcs per middle bag, 20 middle bags per carton

Intended Use:

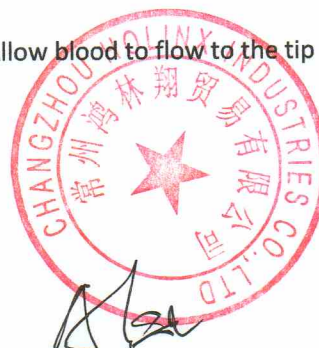
This device is used to perform an intravascular, gravity-controlled transfusion of the blood or its derivatives.

Cautions:

- Read instructions before use.
- Before usage confirm the sterility validity, packing completeness, the LOT number and expiry date.
- Use only if package is undamaged and validity not expired;
- The Blood Transfusion Set should be used immediately after unit package opened.
- To be used by qualified doctor or paramedic only.
- Check the tightness of needle and integrity of components before the use.
- If there is unusual case during transfusion, treat according to the clinical operation protocol.
- For single use. The re-sterilization and/or use by more than one patient may cause a cross-infection.
- Destroy after use.
- Do not use with pressure blood transfusion bag.
- Specially designed for transfusion of blood and blood components. Not recommended for regular IV infusion.
- Use injection connector site only for injecting the medicine intermittently by using an aseptic technique.

Instructions for use:

1. Select the appropriate Blood Transfusion Set with needle for your procedure.
2. Examine individual package for integrity of packaging prior to use. Do not use if packaging has been torn.
3. Before usage, open the unit package using aseptic technique.
4. Close the flow regulator, take off the cap from the spike, pierce the rubber plug of blood container and insert the spike inside. Hang container upside down. Make sure of no leakage.
5. Half fill the drip chamber with blood by gently squeezing and releasing the drip chamber.
6. Open the air vent if used with rigid blood (or its derivative) container and close it when used with soft blood (or its derivative) container.
7. Take off protector of the vein-needle and open roller clamp slightly. Allow blood to flow to the tip of the vein needle removing all air inside the tube.



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8. Shut roller clamp completely and perform vein puncture using an aseptic technique in accordance with your facility's protocol. Fix the vein-needle properly with tape.
9. Regulate the flow by loosening roller clamp.
10. Apply protective caps when procedure is finished.
11. Any used Blood Transfusion Set is considered contaminated and should be disposed of in an approved container immediately after use.
12. To avoid risk of infection, immediately dispose of after single use.

Features:

- Non-toxic;
- Non-pyrogenic;
- Sterile unit packages;
- Cannot be stored at extreme temperature and humidity.

Storage:

Keep away from sunlight. Protect from extreme humidity and heat sources. Not store with organic or chemical solvents. Not store with corrosive gases. Store in dry, cool, good ventilated and clean room, where the relative humidity is less than 80%.

Sample PE bag design:**HOLINX****Disposable Vented
Blood Transfusion Set****L: 155 cm | 18Gx1 1/2"**

1. Swab the container stopper just before the piercing.
2. Close the flow regulator.
3. Take off the spike protector, insert into the blood container and hang it upside down.
4. Half fill the drip chamber with blood by gently squeezing and releasing the drip chamber.
5. Open the air inlet if used with rigid blood container and close it if used with soft one.
6. Partially open the flow regulator to prime.
7. Allow blood to displace the air completely, then close the flow regulator.
8. Perform venipuncture, then fix the needle.
9. Adjust the flow rate.

**STERILE EO****ISO 13485****20drops=1mL ± 0.1 mL**

REF: HBVS18/112

LOT: 20220506

MFG: 20220506

EXP: 20270505

CAUTION:

- Do not resterilize
- Sterile unless package has been opened or damaged
- Do not use if the package is opened or damaged
- Discard after single use
- Do not store in direct sunlight, at extreme temperature, or in high humidity

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MADE IN CHINA

