

HOLINX

Changzhou Holinx Industries Co., Ltd.

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

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

Document No.

HLX/VS-150cm-001

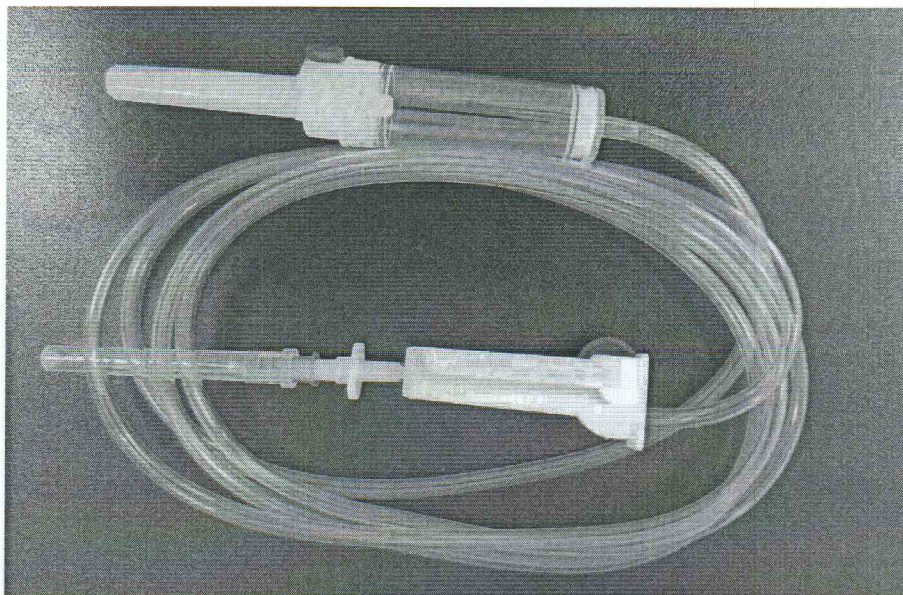
Revision No.

A/1

Date of Revision

2022.11.17

TECHNICAL DATASHEET OF STERILE VENTED IV INFUSION SET WITH NEEDLE FOR SINGLE USE



PRODUCT DETAILS									
Description:	Disposable Vented IV Set, 150 cm, with needle 21GX1½"								
Type:	Luer Slip, without latex bulb								
Drop Factor:	20 drops of distilled water equivalent to 1ml ± 0.1ml (1g ± 0.1g), at 20°C ± 2°C								
Shelf life:	5 years from date of manufacturing								
REF No:	HIVSW/O21								
Composition:	<i>Disposable Vented IV Set with needle is a medical device composed of:</i> <table><tr><td>-Drip chamber;</td><td> <i>-Comes with the <u>spike</u>, which allows effortless pierce of the IV containers rubber plug;</i> <i>- <u>Air vent</u> - is integrated above the drip chamber, allows adequate pressure inside the chamber for smooth, uninterrupted fluid flow;</i> <i>-Transparent flexible <u>drip chamber</u> facilitates rapid adjustment of fluid with further observation/monitoring of fluid flow;</i> <i>-<u>Solution filter</u> – is used to filter particulates (debris, or pathogenic microorganisms that potentially might have been admixed with the IV fluid) and eliminate bubbles.</i> </td></tr><tr><td>-Tubing;</td><td> <i>-Transparent kink resistant tubing smooth and uninterrupted fluid flow.</i> </td></tr><tr><td>-Roller clamp;</td><td> <i>-Moves along the plastic tubing between the drip chamber and the latex-free injection connector site;</i> <i>-Allows a smooth adjustment of the flow rate from a very slow rate to a "wide open" flow rate with high precision.</i> </td></tr><tr><td>-Needle;</td><td> <i>-Luer Slip;</i> </td></tr></table>	-Drip chamber;	<i>-Comes with the <u>spike</u>, which allows effortless pierce of the IV containers rubber plug;</i> <i>- <u>Air vent</u> - is integrated above the drip chamber, allows adequate pressure inside the chamber for smooth, uninterrupted fluid flow;</i> <i>-Transparent flexible <u>drip chamber</u> facilitates rapid adjustment of fluid with further observation/monitoring of fluid flow;</i> <i>-<u>Solution filter</u> – is used to filter particulates (debris, or pathogenic microorganisms that potentially might have been admixed with the IV fluid) and eliminate bubbles.</i>	-Tubing;	<i>-Transparent kink resistant tubing smooth and uninterrupted fluid flow.</i>	-Roller clamp;	<i>-Moves along the plastic tubing between the drip chamber and the latex-free injection connector site;</i> <i>-Allows a smooth adjustment of the flow rate from a very slow rate to a "wide open" flow rate with high precision.</i>	-Needle;	<i>-Luer Slip;</i>
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		-Provides sharp and smooth puncture.			
		-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 IV Set.	

Materials: PP, PVC, PE, ABS, PTFE, Stainless Steel.

Sterilization: EO (Ethylene Oxide)

Product standards: ISO 8536-4-2019, GB 8368, ISO 7864-2016(indicate the general applicable standards)

Certificates: CE, ISO 13485

Classification: MDD 93/42/EEC, Class IIa

Packaging: Single PE bag, 25 pcs per middle bag, 20 middle bags per carton

Intended Use:

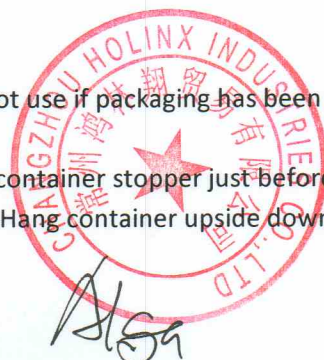
Its purpose is to transfer the intravenous (IV) fluid by gravitational force.

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 IV 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 infusion, 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 infusion bag.
- Do not use for transfusion of the blood or its derivatives.
- Use injection connector site only for injecting the medicine intermittently using aseptic technique.

Instructions for use:

1. Select the appropriate IV 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, and swab the container stopper just before the piercing.
5. Pierce the rubber plug of infusion container and insert the spike inside. Hang container upside down. Make sure of no leakage.



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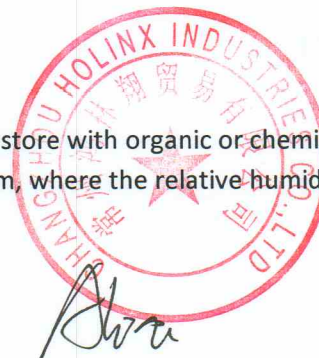
6. Half fill the drip chamber with solution by gently squeezing and releasing the drip chamber.
7. Open the air vent if used with hard (glass) IV solution container and close it when used with soft IV solution container.
8. Take off protector of the vein-needle and open roller clamp slightly. Take out the solution through the vein needle to remove air inside tube completely.
9. 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.
10. Regulate the flow by loosening roller clamp.
11. Apply protective caps when procedure is finished.
12. Any used IV Set is considered contaminated and should be disposed of in an approved container immediately after use.
13. 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%.



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Sample PE bag design:

Editor:

Audit:

Approve:

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SET PENTRU PERFUZIE

L: 150 cm | 21Gx1 1/2" | Fără manșon

1. Tamponați dopul recipientului înainte de străpungeră.
2. Închideți regulatorul de debit.
3. Detașați protectorul pentru vârf, introduceți-l în recipientul cu soluție și poziționați-l cu capul în jos.
4. Strângând și eliberând ușor godeul de picurare, umpleți cu soluție până la jumătatea camerei acestuia.
5. Deschideți orificiul de admisie a aerului dacă este utilizat cu un recipient de soluție rigid și închideți-l dacă este folosit cu unul maleabil.
6. Deschideți parțial regulatorul de debit pentru amorsare.
7. Lăsați soluția să deplaseze complet aerul, apoi închideți regulatorul de debit.
8. Efectuați străpungera venei, apoi fixați acul.
9. Reglați debitul.



STERILE EO

ISO 13485



20 Picături=1mL±0,1 mL

- Netoxic
- Apirogen
- De unică folosință
- Luer-Slip

REF: HIVSW/O21
LOT NO: 20220506
PROD: 20220506
EXP: 20270505

Precauție:

- Nu resterilizați
- Steril până când ambalajul nu a fost deschis sau deteriorat
- Nu utilizați dacă ambalajul este deteriorat sau a fost deschis anterior
- Neutralizați după utilizare
- Nu depozitați la lumina directă a soarelui, la temperaturi extreme sau la umiditate ridicată
- A nu se utiliza pentru transfuzie de sânge sau derivați sanguini

EC REP

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PRODUS ÎN CHINA