

IFU of Intravenous Cannula (with/ without safety feature) manufactured by Chiron Surgimed Pvt. Ltd.

General Device Description: This device is used for infusing into human body, intravenous body fluids such as glucose, saline solutions or blood. This device is to be connected with I.V. Set for the infusion of fluids into the human body. This product is having different gauges from 14G, 16G, 17G, 18G, 20G, 22G, 24G and 26G. Each gauge will have the standard color code. Any intermittent drug to be administered can be administered through port of Intravenous Cannula (with/ without safety feature) which comprises of one-way valve that opens and closes with the pressure of medicine being administered.

Intravenous Cannula (with/ without safety feature) is a device for access to the human circulatory system for introduction of fluids or medicines. Intravenous Cannula (with/ without safety feature) comprises of a short flexible plastic tube (the Catheter), which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn from vein and tube remains inserted in to human circulatory system.

Product Name: Intravenous Cannula (with/ without safety feature)

Brand Names: Chiro-Vein, Chiro-Neo, Chiro-Vein Safety

Variants:

1. I.V. Cannula with Wings & With Port
2. I.V. Cannula with wings & without port
3. I.V. Cannula without wings & without port
4. I.V. Cannula with Small Wings & Without Injection Port For Neonates
5. I.V. Cannula with Suturable Wings & With Port
6. I.V. Cannula with wings, with port & Safety feature
7. I.V. Cannula Without Wings, Without Port and with Safety Feature
8. I.V. Cannula with Small Wings & Without Port (Intra Type)
9. I.V. Cannula With Small Wings With Suture Holes & Without Port (Arterial Catheter Type)
10. I.V. Cannula with Suturable Wings & With Port and with Safety Feature
11. I.V. Cannula Without Wings, Without Port and With Safety Feature (Active)
12. I.V. Cannula Without Wings & Without Port (Pen Type Cap)
13. I.V. Cannula with Integrated 3 Way Stop Cock
14. I.V. Cannula Without Wings, Without Port and With Safety Feature (Tele Type)

Intended use:

I.V. Cannula is a device for access to the human circulatory system for introduction of fluids and/or withdrawal of blood samples. I.V. Cannula comprises of a short flexible plastic tube (the Catheter), which is inserted into a vein over a hollow introducer needle, after which the needle is withdraw and discarded.

Material of construction:

Component	Material
Catheter	Fluorinated ethylene propylene (FEP)/PTFE/PU
Teflon Holder	Delrin
Wing Housing	Poly Propylene
Needle Hub	Poly Propylene for IV Cannula without safety feature K-Resin for IV Cannula with safety feature
Needle Cover	Poly Propylene
Hub cover	Poly Propylene for IV Cannula without safety feature K-Resin for IV Cannula with safety feature
Threaded Stopper	HDPE + Master Batch
Needle	Stainless Steel
Silicone tube	Silicone
Injection Port Cap	LDPE
Neon Housing	Poly Propylene
On Needle Hub	Poly Propylene
Nano wings Housing	Poly Propylene
Silicone Lubricant (Viscosity-ctsk)	Silicone
Suturable Wings Housing	Poly Propylene
Safety Wings Housing	Poly Propylene
Metal clip	SS
Porex Filter	P. E
Intra wing Housing	Poly Propylene
Intra Needle Cover	Poly Propylene
Handle	HDPE
Channel	PC
Pen Needle Cover	Poly Propylene
Round Body Cap	Poly Propylene

Small without wings-Housing	Poly Propylene
Slider Needle Hub	K-Resin
Safety Barrel	PC
Arterial Wing Housing	Poly Propylene
Tube Holder	Polyacetal
Steel ball	SS (304 AISI)
Slider	ABS
Suspension Tube	Silicone
Needle Hub Case	K-RESIN
Intra Needle Hub	Poly Propylene
Spring Cover	PP
Locking Clip	Polyacetal
Compression Spring	SS
Barrel tip	PC

Intended Medical Indication:

- Infusion of IV Fluid
- Infusion of IV Drugs administration
- Intravenous blood or blood products administration for short duration
- To deliver the fluids in the patient who are unable to take nutrients/fluids orally
- Certain types of drugs used in cancer treatment may be given by infusion through the vein and into the bloodstream by intravenous means (IV)

Contraindications:

- Administration of highly viscous fluid.
- Large blood transfusion
- Not to be used in patients with known hypersensitivity to any of the materials used.
- Administration of fluid or drugs which are irritant to the materials of the product.
- Clot obstructed Vein, Thrombosis, phlebitis
- Stenosis of Vein, Hematoma
- Severe Coagulopathy

Known Characteristics of Device in case of re-use:

- Difficult to penetrate the needle during use and probability of folding back of catheter
- Any infectious disease can transfer

Intended Patient Population:

All age group such as – Neonates, Pediatrics & Adults

- 24 – 26G – Neonates (0 - 1 Month)
- 22G – Pediatrics (1 Month up to 18 years)
- 14 – 20G – Adults (18 years and older)

Intended User: A qualified doctor or a paramedic

Use Environment: Proper healthcare set up

Instructions for Use:

- It is applicable for 14 G, 16 G, 17 G, 18 G, 20 G, 22 G, 24 G & 26 G.
- Select proper type and size of Intravenous Cannula (with/ without safety feature). Always use the smallest size cannula possible to adequately deliver the desired I.V. Fluids.
- Carefully select and clean the venipuncture site.
- Inspect cannula package for integrity and expiry and then remove cannula from package. Remove needle cover and grip the cannula from needle hub projections.
- In case of flushing, use a normal saline solution as per standard procedure
- Insert cannula into the vein at a low angle and check for blood in flashback chamber to ensure proper venepuncture.
- Advance the catheter into vein and simultaneously withdraw the needle gently.
- Do not try to reinsert a partially or completely withdrawn needle.
- Avoid blood spillage by pressing the finger on the vein on or above the catheter tip.
- Replace needle with either the I.V. infusion set line or the luer lock plug.
- Discard the needle in an appropriate waste container.
- For the IV cannula containing wings, tape down the wings of the cannula to the patient skin.
- Cover the puncture site with a sterile dressing.
- For I.V. cannula with injection port drugs can be injected intermittently with the help of a syringe through the injection port after removing the port cap.
- For I.V. cannula with injection port the injection port cap should remain closed when not in use.

- Inspect venipuncture site regularly for any reactions and check all connections.

Intended Clinical Benefits to the Patients:

- 72 hours of Indwelling Time.
- Saves Patients from multiple vein insertions.
- Separate injection port with cap for medicine introduction to avoid contamination.
- Easy Movement of IV placement site without the risk of puncture of Vein
- MRI (Magnetic resonance Imaging) compatible
- Biocompatible products
- Certain types of drugs used in cancer treatment may be given by infusion through the vein and into the bloodstream by intravenous means (IV)
- Products with safety feature prevents needle stick injury

Performance Characteristics:

- Administration of fluids depends on the size of the catheter chosen and the flow of the fluids will be more in larger diameter catheter.
- The provided cannula of 24G and 26G are used for neonates because of smaller vein.
- Proper tensile strength for the needle and the Catheter and there won't be any leakage from the joint of catheter and wing housing.
- Proper flashback chamber.

Accessories which can be used with the device:

- Intravenous Cannula (with/ without safety feature) can be used along with connecting accessories such as 3-way stopcock, Syringes, IV set, BT set.

Warnings:

- For single use only
- Read instructions before use.
- Check expiry date prior to use.
- The product should be used according to the instructions for use
- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/ or functional damage to device or packaging which leads to leakage of administered fluids or drugs.
- Don't use the product if package is damaged

- The product is guaranteed non- toxic, sterile & non- pyrogenic if the package has not been opened or damaged.
- Discard after use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and country laws and regulations.
- Ensure proper disposal of product and packing after use.
- Use the product immediately after opening the individual blister packing.
- The product should not be reprocessed.
- The product should be used by a qualified doctor or a paramedic.
- Store in a cool and dry place. Protect from excessive heat or direct sunlight.

Cautions:

- Do not try to reinsert a partially or completely withdrawn needle.
- Discard needle in proper container
- The provided cannula of 24G and 26G are used for neonates.
- Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or bacterial infections
- Chiron disclaims any responsibility for possible consequences resulting from improper use

Limitations:

- Intravenous Cannula (with/ without safety feature) can cause needlestick injury.

Potential Side Effects:

- Allergic Reaction
- Pain as a symptom of soreness and tenderness at the site of use
- Infection of improperly managed wounds.
- Bleeding after the introduction of cannula.

Disposing instructions:

Discard the needle and the used Intravenous Cannula (with/ without safety feature) in proper waste containers such as puncture-resistant containers & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling

bio- medical waste, as improper disposal can lead to bio-hazard.

Return of Device:

The return of defective device should be carried out within a week of receipt of the product along with the evidence or damaged product and the product should not have been used under any circumstances, at any condition.

Duration of Use:

72 hours (It is recommended to withdraw the Intravenous Cannula (with/ without safety feature) after 96 hours from the patient. The user is accountable for any type of problem taking place in case of use after 96 hours of the same device.)

Storage Condition:

Temperature: 05-45°C and Humidity: 60±5%

Keep away from sunlight and keep in dry condition.

Shelf Life of the Device:

05 Years

Type of Sterilization:

This device is supplied as sterile by using ETO Sterilization.

Notice to Users and/or Patients:

In the event of malfunction of the device or changes in its performance that may affect safety, or any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

How device is supplied:

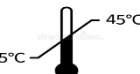
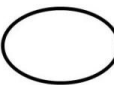
Intravenous Cannula (with/ without safety feature) is packed 1 unit/piece in P.V.C. film for blister and pouch packaging or medical grade paper pouch packaging.

Name	Units per Box (Secondary packaging)	Units per Box (Tertiary packaging)
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I.V. Cannula with wings & with port	100 Pcs/box	1000 Pcs/carton
I.V. Cannula with wings & without port	100 Pcs/box	1000 Pcs/carton
I.V. Cannula without wings without port	100 Pcs/box	1000 Pcs/carton
I.V. Cannula with Small Wings & Without Injection Port For Neonates	50 Pcs/box	1000 Pcs/carton
I.V. Cannula with Suturable Wings & With Port	100 Pcs/box	1000 Pcs/carton
I.V. Cannula with wings, with port & Safety feature	50 Pcs/box	500 Pcs/ carton
I.V. Cannula Without Wings, Without Port and with Safety Feature	50 Pcs/box	500 Pcs/ carton
I.V. Cannula with Small Wings With Suture Holes & Without Port (Arterial catheter type)	50 Pcs/box	500 Pcs/ carton
I.V. Cannula with Small Wings & Without Port (Intra Type)	100 Pcs/box	1000 Pcs/carton
I.V. Cannula with Suturable Wings & With Port and with Safety Feature	50 Pcs/box	500 Pcs/ carton
I.V. Cannula Without Wings, Without Port and With Safety Feature (Active)	100 Pcs/box	500 Pcs/ carton
I.V. Cannula Without Wings & Without Port (Pen Type Cap)	50 Pc/box	100 Pc/box
I.V. Cannula with Integrated 3 Way Stop Cock	100 Pcs/box	1000 Pcs/carton
I.V. Cannula Without Wings, Without Port and With Safety Feature (Tele Type)	100 Pcs/box	1000 Pcs/carton

Explanation of Symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Medical device (Indicates the item is a medical device)		Latex free (Indicates a medical device that is Latexfree)
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Date of manufacture (Indicates the date when the medical device was manufactured)

	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Use-by date (Indicates the date after which the medical device is not to be used)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch code (Indicates the manufacturer's batch code so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)
	Non-pyrogenic (Indicates a medical device that is non-pyrogenic)		Country of manufacture (To identify the country of manufacture of products)
	Do not use if package is damaged and consult instructions for use (Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information)		CE Mark
	Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.)		Single sterile barrier system (Indicates a Barrier single sterile system)

	Keep dry (Indicates a medical device that needs to be protected from moisture)		Authorized representative in the European Community / European Union (Indicates the authorized representative in the European Community / European Union) CMC Medical Devices & Drugs S.L. C/ Horacio Lengo, Nº18, CP 29006, Málaga-Spain Tel: +34951214054; Email: info@cmcmedicaldevices.com
	Manufacturer (Indicates the medical device manufacturer) Chiron Surgimed Pvt. Ltd. Survey No. 883/1, GIDC Road No. 3, Mansa-382845, Dist. Gandhinagar, Gujarat Contact No. : +91-8735918291 Email : info@chironsurgimed.com Website: www.chironsurgimed.com		Refer to instruction manual/booklet

REVISION HISTORY:

Sr. No.	Document Name	Document No.	Issue No.	Issue Date	Revision No.	Revision Date	Reason for Amendments
1.	Instruction for Use	CSL/IFU/IV C/00	01	01.08.2024	00	--	Initial Issue
2.	Instruction for Use	CSL/IFU/IV C/00	01	01.08.2024	01	23-04-2025	As per reviewer's comment to add contact details under manufacturer column.