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## 百新 (Bexin

百合医疗科技(武汉)有限公司

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# **Technical Data**

## (Disposable needle free infusion connectors)

## 1. Device Description

An intravenous infusion, transfusion.

Item Code: SJ-NY00; SJ-NY01; SJ-NY02; SJ-NY03; SJ-NY04

#### 2. Intended Use

The product is used to close the transfusion port, supply liquid medicine when the adaptor is closed and prevent the transfusion system from polluting during intravenous infusion therapy.

#### 3. Expiration Date

Shelf life: 3 years.

### 4. Device Specification

Injection joints are divided into Y type. The product is composed of connector and pipeline, the connector is composed of upper cover, valve, lower cover and protective cap. According to the number of pipes, there are single pipe, double pipe, three pipe and four pipe. The needle free connector-Y type has a split septum design that adheres to guidelines for reducing CRBSIs set by the Centers for Disease Control and Prevention (CDC) and the International Nosocomial Infection Control Consortium (INICC).

Item code	Extension	Length	Diameter
SJ-NY01	1	18 cm	
SJ-NY02	2	15 cm	1.49 mm
SJ-NY03	3	15 cm	
SJ-NY04	4	15 cm	

- SJ-NY00 Needle-free closed system connector.
- Without non-return valve
- Medical grade silicone seal with a dynamic closure when connecting the syringe.
- Withstands pressures of 100 PSI.
- Infusion rate 420 ml/min.
- Seal without dead space.
- Split septum valve.
- Compatible with lipids, cytostatics, blood derivatives and blood components

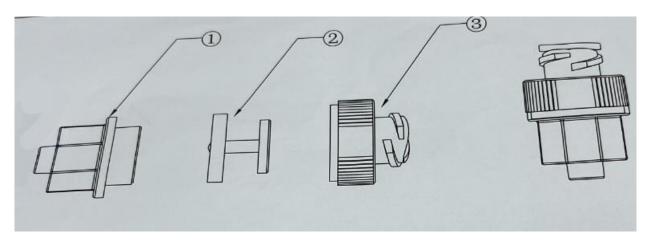
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- 18 G internal Luer seal.
- Luer lock and luer slip connection.
- With independent closure on each extension.
- Latex free.
- DEHP free.
- Sterile.
- Single use.



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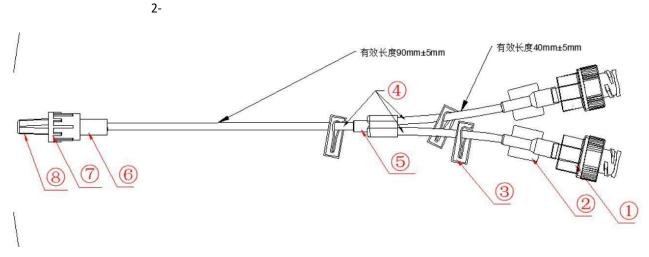
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- 1- lower cover; 2- valve; 3- upper cover.
  - a) Structure drawing of infusion joint



1- infusion joint; 2- Female connector; 3- Stop clamp; 4 - the tube body; 5- Conversion connector; 6-Male connector; 7 - lock the connector; 8 - protecting cap.

b) Schematic diagram of infusion joint of four pipelines

### 5. Classification

Class II a, according to Appendix 9 of the MDD Directive, Rule 2: Disposable needle free infusion connectors is

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non-invasive devices used to transport blood, the product can be connected with infusion pump for use.

All non-invasive devices intended for channelling or storing blood. body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

if they may be connected to an active medical device in Class IIa or a higher class

#### **Picture**



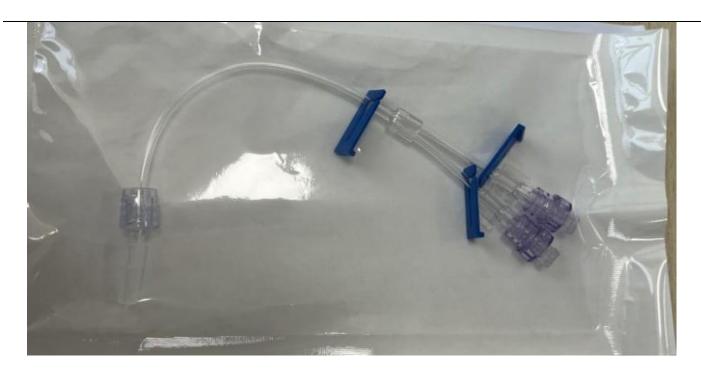


Fig.1 Packaging diagram of Disposable needle free infusion connectors



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## **Bill of Material**

Product part	Mate rial	Connect with blood
upper cover	PC	Indirect contact
lower cover	PC	Indirect contact
valve	Silicone Rubber	Indirect contact
The male connector	PC	Indirect contact
Lock the connector	PC	No
Crossover sub	PC	Indirect contact
Check the flow clip	ABS	No
Protecting cap	PP	No
Female connector	TPU	Indirect contact
The tube body	TPU	Indirect contact

## 6. Device package

Paper and plastic bags are used for the primary packaging. The paper and plastic bags are made of 65g medical coated paper on one side and PE/PET composite film on the other side.

The middle packaging uses carton and the material is single corrugated cardboard.

Carton size of infusion connectors without tubing: 210mm×155mm×100mm, each medium package contains 50 single packages.

Carton size with tubing infusion connectors: 210mm×155mm×100mm, each package contains 20 single packages.

The big package is made of carton and the material is double corrugated cardboard.

Carton size of infusion connectors without pipeline: 530mm×440mm×340mm, each large package contains 20 medium packages, namely 1000 single packages. Carton size with pipeline infusion connectors: 530mm×440mm×340mm, each large package contains 20 medium packages, that is 400 single packages