
	Product specification	PS 310-0116-01	Revision: 3.0
	SPIKE FOR SINGLE USE - CHIRAPLUS		Valid from: 16.08.2022 Page: 1/5

## SECTION I: PRODUCT DESCRIPTION

- 1.1 Product name: **Spike for single use**
- 1.2 Trade mark: **CHIRAPLUS**
- 1.3 Product type: sterile, for single use, non-toxic, non-pyrogenic
- 1.4 Intended purpose: Spike for single use is intended for pharmaceutical preparations – transmit fluids from one container to another (e.g., transfer medication from the vial to the syringe or from the syringe to the vial), mixing fluids or dissolve dry substances in the vials.
- 1.5 Product classification: based on [MDR 2017/745, Annex VIII](#) as **Class Is, Rule 2**
- 1.6 Compatible devices: [Syringes for single use](#).  
Spike for single use is commonly used with syringe, that can be easily attached because of connectors in accordance with [EN ISO 80369-7:2021](#), in order to withdraw fluids from vial or ampule safely and without air pollution.  
These products are not accessories / parts of our product Spike for single use, but are available as product itself in our portfolio.
- 1.7 Versions:
- GREEN type:** It is a vented dispensing pin for injection & withdrawing fluids from vials or semi-rigid containers. It has air filter - hydrophobic bacteria filter (0.1µm) - protection against microbial contamination. Ensure easy handling through ergonomic design, simple one-hand handling (Open & Close).
- BLUE type:** It is vented dispensing pin for filtered injection or filtered withdrawal fluid from vials or semi rigid containers with 0.1µm air filter & 5.0µm fluid (solution) filter - protection against particles during withdrawal. Ensure easy handling through ergonomic design, simple one-hand handling (Open & Close).
- RED type:** It is vented dispensing pin for filtered injection or filtered withdrawal fluid from vials or semi rigid containers with 0.1µm air filter & 5.0µm fluid (solution) filter - protection against particles during withdrawal. Ensure easy handling through ergonomic design, simple one-hand handling (Open & Close). This variant is used for handling of chemotherapeutics as its housing material is compatible with chemo medicines.



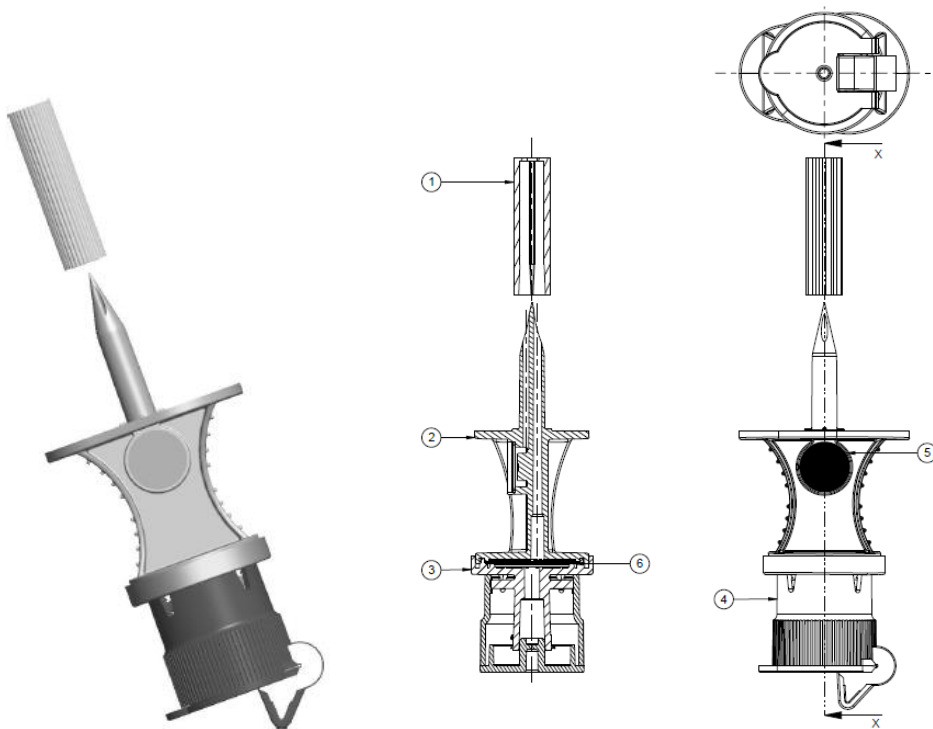
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1.8 Technical data:


Material: The parts of spike for single use are made of medically harmless materials.

- |  |  |
|--|--|
| Spike (body) / spike holder                      | - ABS (Acrylonitrile Butadiene Styrene)  |
| Spike (body) / spike holder ("chemo" = red type) | - Copolymer ETT                          |
| - air filter (0.1µm)                             | - PTFE (Polytetrafluorethylene) membrane |
| - fluid (solution) filter (5.0µm)                | - PET (Polyethylene terephthalate)       |
| Snap cap   | - PP (Polypropylene)                     |
| Spike cover                                      | - PP (Polypropylene)                     |
- Product is PVC free / LATEX free / DEHP free.

1.9 Design:



- |                   |  |
|-------------------|--|
| Spike cover (1):  | protect tip of spike, contamination during handling is preventing, natural color / transparent, inner diameter 4,0+0/-0,1mm, length 22,5+/-0,1mm |
| Spike (body) (2): | has sharp and damage free tip used for insertion into rubber stopper of vial during withdrawal of fluids, has ribs for proper gripping           |
| Spike holder (3): | 6% cone comply with <a href="#">EN ISO 80369-7:2021</a> , positioned between snap cap and spike (body), length 15,1+/-0,1mm                      |
| Snap cap (4):     | protect taper of spike holder, contamination preventing, open / close system   |
| Air filter (5):   | white PTFE membrane filter 0.1µm integrated into the spike body, hydrophobic bacteria filter for preventing entry of microorganisms and to       |

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lower negative pressure while removing contents from the vial. It does not leak at 1,0 bar air pressure

Fluid filter (6): PET hydrophilic filter 5.0µm

Color: green / blue / red

1.10 Sterilization: Spikes **for single use** are sterilized by ethylene oxide in its final package using validate sterilization process (EN ISO 11135:2014) insuring SAL at least  $10^{-6}$  (EN 556-1:2001).

1.11 Production: Production takes place in clean rooms class ISO7 according to EN ISO 14644-1:2015.

## SECTION II: PERFORMANCE SPECIFICATION

2.1 Dimensions: Spike holder: length 15,1+/-0,1mm  
Spike cover: inner diameter 4,0+0/-0,1mm, length 22,5+/-0,1mm  
Air filter: PTFE membrane filter 0.1µm  
Fluid filter: PET hydrophilic filter 5.0µm

2.2 Packaging:

<i>Product</i>	<i>REF code CHIRANA</i>	<i>Blister dimensions (mm)</i>	<i>Pieces in Box</i>	<i>Box dimensions (mm)</i>	<i>Pieces in Carton</i>	<i>Carton dimension (mm)</i>
Infusion spike (red)	CHIS01	105 x 55	100	215 x 205 x 160	1 000 (10 x 100)	850 x 450 x 225
Infusion spike (blue)	CHIS02					
Infusion spike (green)	CHIS03					

The package of the Spike **for single use** and its integrity ensures the sterility and usability for the period of 5 years provided the transport and storage condition.

On the lower part of package is heat-weld able paper which allows the passage of the sterilized ethylene oxide. On the upper part of package is transparent shapeable foil, which is welded together with the laminated paper on its circumference.

## SECTION III: PRODUCT IDENTIFICATION

3.1 Identification of product (LOT):

The product is identified by product name, type (product code) and lot number (LOT). Lot number of the products and production date can be defined following:


**1XXXXYYM** or **3XXXXYYM**

where: first number 1 or 3 is identification number of production line

XXXX is serial number of LOT

YY last number of year

M is month of production form the table:

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<i>Month</i>	<i>Code</i>	<i>Month</i>	<i>Code</i>
January	A	July	G
February	B	August	H
March	C	September	K
April	D	October	L
May	E	November	M
June	F	December	N

3.2 Date of production in this format: **YYYY-MM**

where: YYYY is year of production

MM is month of production (01-12)

#### **SECTION IV: TRANSPORT AND STORAGE**

4.1 Transport condition:

The transport of the packed product can be carried out only in covered, clean and dry means of transport at the temperature +5°C - +35°C. Take care of warning data marked on the package during the transport.

4.2 Storage conditions:

The Spike for single use should be stored in dry, ventilated, dust-free rooms which are protected from the straight effect of the solar radiation at the temperature +5°C - +35°C. No organic solvents and chemicals are allowed to be stored with the them.

#### **SECTION V: DELIVERY, GUARANTEE**

5.1 Certificate of quality:

With each delivery it is possible (according to customer requirement) to issue Certificate of quality.

Deliveries are inspected after agreement with the customer by statistical acceptance according to ISO 2859-1:1999.

5.2 Shelf-life:


The manufacturer grants the guarantee for the period of usability of the product for 5 years since the production date, provided the prescribed storage and transport conditions according to point IV.

Period of usability (expiration) is marked on packaging with form:

⌘ **YYYY - MM**

where: YYYY is last year of usability

MM is the last month of usability (01-12)

 <b>CHIRANA</b> <i>T. Injecta</i>	<b>Product specification</b>	<b>PS 310-0116-01</b>	Revision: <b>3.0</b>
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## SECTION VI: RELATED STANDARDS

[MDR 2017/745](#)

EN ISO 13485:2016

[EN ISO 14971:2019](#)

[EN ISO 80369-7:2021](#)

EN ISO 11135:2014

EN ISO 14644-1:2015

[EN ISO 15223-1:2021](#)

[EN ISO 11607-1:2020](#)

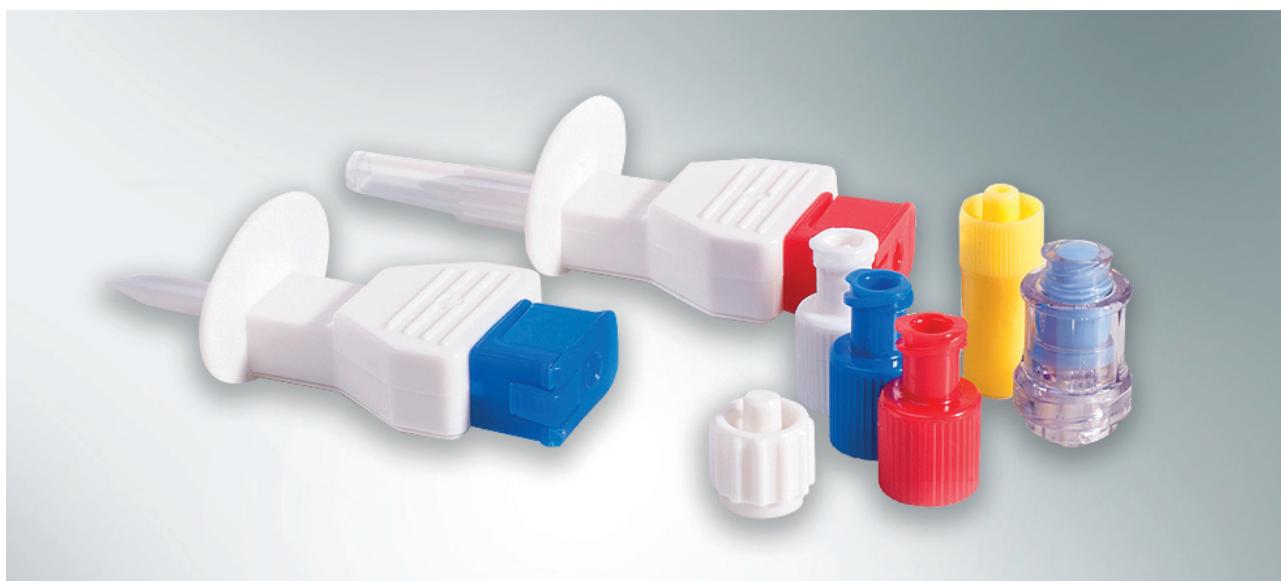
ISO 2859-1:1999

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## CHIRAPLUS™ Spikes | Injection ports | Stoppers



- ✓ spikes intended for comfortable and safe drug manipulation
- ✓ ports offer additional drug administration when applied with other devices
- ✓ combistopper and stopper give a short-term option for storage or transfer of solution

Item	Pieces per Box	Pieces per Case	Item Code
Infusion spike RED air			
0,2 µm + 5 µm solution filter	25	400	CHIS01
Infusion spike BLUE			
air 1,2 µm + 5 µm solution filter	25	400	CHIS02
Infusion spike GREEN air 1,2 µm filter	25	400	CHIS03
Transflo spike	100	1000	CHTS01
Needle free injection port	50	2500	CHNF01
Injection port	100	5000	CHIP01

## CHIRAPLUS™ Spikes | Injection ports | Stoppers

Item	Pieces per Box	Pieces per Case	Item Code
Combistopper RED	100	5000	CHCS01
Combistopper BLUE	100	5000	CHCS02
Combistopper WHITE	100	5000	CHCS03
Stopper Luer lock	100	5000	CHLL01

✓ intended for range of application in IV administration