

# PRODUCT INFORMATION

## SAFETY BLOOD COLLECTION SET + HOLDER

### SPECIFICATION

#### PRODUCT DESCRIPTION

The SAFETY Blood Collection Set + Holder is a single-use, sterile, winged needle bonded to a flexible tubing with a luer connector and a holder. It is individually wrapped and sterile. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions. The SAFETY Blood Collection Set + Holder does not contain any components made of dry natural rubber.

It is a product version of the SAFETY Blood Collection/Infusion Set.

#### INTENDED USE

The SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The SAFETY Blood Collection/Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

#### CLASSIFICATION OF DEVICE

EU classification: medical device (acc. to MDD 93/42/EEC)  
MDD Class IIa

#### CE-MARK / APPLIED STANDARDS / PRODUCT CERTIFICATIONS

All standards required for CE certification are fulfilled.  
Notified Body: TÜV Süd, Germany  
CE-Mark, US FDA, all others individual per country

#### FIELD OF APPLICATION

Routine venous blood collection and  
short-term infusion after removal of male luer accessories.



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#### MATERIALS

Product Part	Material (basic description)
Cap	Polyethylene and Polypropylene
Protector	Polycarbonate
Needle	Stainless steel SUS-304
Wings, tubing	PVC (TOTM)
Hub / luer connector	ABS
Glue	Epoxy
Lubricant	Silicone oil
<b>Luer Adapter:</b>	
Hub	Polypropylene
Rubber seal	Synthetic rubber
Cannula	Stainless steel SUS-304
Holder	Polypropylene

#### LEGAL MANUFACTURER

**Greiner Bio-One GmbH**  
Bad Haller Straße 32  
4550 Kremsmünster  
Austria

#### PRODUCER (PHYSICAL MANUFACTURER)

**Nipro (Thailand) Corporation Limited**  
10/2 Moo 8 Bankgnomko, Sena, Phra, Nakhon Si  
Ayutthaya 13110, Thailand

#### STERILITY

**Sterility Level:** Sterile (SAL 10<sup>-6</sup>)

**Method:** ETO (sterilisation with Ethylene Oxide)

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#### PACKAGING

- ☞ **Graphical symbols used:** according to EN ISO 15223-1, for use in the labelling of medical devices.
- ☞ **Single package:** Pouch. Plastic material.
- ☞ **Shelf box:** Cardboard material.
- ☞ **Shipping carton:** double corrugated board.

	Single package	Shelf box	Shipping carton
SAFETY Blood Collection Set + Holder	1 pc.	24 pcs.	240 pcs.

#### LABELLING

**Graphical symbols used:** according to EN ISO 15223-1, for use in the labelling of medical devices.

**Labelling information:** According to the requirements of the relevant EU and FDA guidelines.

#### Lot numbers

For example "17G11". Meaning of digits:

Digits 1-2	Digit 3 (letter)	Digits 4-5
17	G	11
Represents manufacturing year. 17 = 2017	Represents manufacturing month. G = 7th letter in the alphabet. G = therefore "July"	Represents manufacturing day. 11 = 11th day of the manufacturing month.

#### IFU as part of labelling

	Available (Yes / No)	Enclosed with product (Yes / No)	Available via Website (Yes / No)
Graphic IFU	Yes	No	Yes
Full (verbal) IFU	Yes	Yes	Yes

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#### SHELF LIFE

3 years from date of manufacturing. Expiry date is 3 years minus one day from the manufacturing date.

#### RECOMMENDED STORAGE CONDITIONS

Store the SAFETY Blood Collection Set + Holder at 4-36°C (40-97°F) before use.  
Avoid exposure to direct sunlight.

#### ADDITIONAL PRODUCT INFORMATION

##### Additional information concerning materials

- Product is not made with DEHP
- Product is not made with natural rubber latex.
- Product is colour-coded for identification of gauges, in accordance with ISO 6009:
  - 21G: Green
  - 23G: Blue
  - 25G: Orange
- Product doesn't contain components of animal origin



##### Additional information for use of the device

*Maximum Priming Volume (ml)			
Tubing	21G	23G	25G
10 cm / 4 inch	0.3	0.3	-
19 cm / 7.5 inch	0.4	0.4	0.4
30 cm / 12 inch	0.6	0.6	0.6

*Maximum Flow Rate (ml/min)			
Tubing	21G	23G	25G
10 cm / 4 inch	20.8	9.6	-
19 cm / 7.5 inch	20.4	9.4	5.5

\* values established with water

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### SILICONISATION

On the patient end of the needle as well as on the needle of the Luer Adapter

### NEEDLE INFORMATION

Gauge Type of needle	wall	Nominal outer diameter	Nominal bevel length	Nominal needle length
21G	Thin wall	0.8 mm	2.70 mm	¾" (19 mm)
23G	Thin wall	0.6 mm	2.20 mm	¾" (19 mm)
25G	Thin wall	0.5 mm	1.75 mm	¾" (19 mm)

### RECOMMENDED COMPONENTS FOR USE WITH THE DEVICE

 **VACUETTE®** Blood Collection Tubes