

PRODUCT INFORMATION

SAFETY BLOOD COLLECTION / INFUSION SET

SPECIFICATION

PRODUCT DESCRIPTION

The SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged needle bonded to a flexible tubing with a luer connector. The SAFETY Blood Collection/Infusion Set is individually wrapped, sterile and can be used with a luer system (e.g. HOLDEX®). The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions. The SAFETY Blood Collection/Infusion Set does not contain any components made of dry natural rubber.

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
Luer cap	Polypropylene
Needle	Stainless steel SUS-304
Wings, tubing	PVC (TOTM)
Hub / luer connector	ABS
Glue	Epoxy
Lubricant	Silicone oil

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 10⁻⁶)

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 / Infusion Set	1 pc.	50 pcs.	1000 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/Infusion Set 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 from animal origin



Additional information for use of the device

Tubing	*Maximum Priming Volume (ml)		
	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

Tubing	*Maximum Flow Rate (ml/min)		
	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

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®** Luer Adapter
 Blood Culture Holder
 Standard Holder
-  **HOLDEX®**
-  **VACUETTE®** Blood Collection Tubes