

	Product Technical Data IMPROSAFE Blood Collection Set	Document No	
		Page	1/3
		Version	A/2

Product Technical Data

Product Name IMPROSAFE[®] Blood Collection Set

Item Code, specification, color code and package information

Product Code	Description	Needle Gauge * Needle Length(Inches) * Tubing Length(Inches)	Wing Color/shield color	Box/Carton Qty
596121190	Blood Collection Set	21G*3/4*7"	Green	100/2000
596121300	Blood Collection Set	21G*3/4*12"	Green	100/2000
596123190	Blood Collection Set	23G*3/4*7"	Blue	100/2000
596123300	Blood Collection Set	23G*3/4*12"	Blue	100/2000
596125190	Blood Collection Set	25G*3/4*7"	Orange	100/2000
596125300	Blood Collection Set	25G*3/4*12"	Orange	100/2000

Note: the specification is not limited to the above table. Refer to product list for full specification.

Subject and application

The products and evacuated blood collection tube/ syringe are used together for the collection of venous blood. The winged needles is designed with a safety shield which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needle stick injury. The Pre-attached Holder is designed to aid in protection against accidental non-patient needle injury and blood splatter. It also helps to improve the working efficiency as it eliminates the procedure of holder assembling.

The products are single-use, sterile, winged needle bonded to a flexible tubing with luer adapter. They're sterile and non-pyrogenic.

Products	Accessories	
	Safety Shield	Needle Holder
IMPROSAFE [®] Blood Collection Set	YES	NO

Product photo



 Product Technical Data IMPROSAFE Blood Collection Set	Document No	
	Page	2/3
	Version	A/2

Structure and raw material

- 1—rubber sleeve: synthetic rubber
- 2—tube needle: Stainless steel
- 3—needle holder: Polypropylene
- 4—hub: acrylonitrile butadiene styrene
- 5—luer adapter: PCTG
- 6—tubing: Polyvinyl Chloride
- 7—safety shield: polypropylene
- 8—butterfly : Polyvinyl Chloride
- 9—vein needle :Stainless steel
- 10—vein needle cover : polypropylene

Specification of needle

Conform to the specification of the following table; (Refer to GB15811 for diameter specification.)

Table 1 Unit : mm

Type	Size	Outer diameter		Inner diameter
		Min	Max	Min
Vein end needle	0.55 (24G)	0.550	0.580	0.343
	0.6 (23G)	0.600	0.673	0.370
	0.7 (22G)	0.698	0.730	0.440
	0.8 (21G)	0.800	0.830	0.547
	0.9 (20G)	0.860	0.920	0.635
Tube end needle	0.9(for all tube end needle)	0.880	0.920	0.560

Prime volume

Gauge	Tubing (inch)	Volume (ml)
21G	7"/12"	0.22/0.34
22G	7"/12"	0.22/0.34
23G	7"/12"	0.22/0.34
25G	7"/12"	0.22/0.34
27G	7"/12"	0.22/0.34

Raw material certifications

	Product Technical Data IMPROSAFE Blood Collection Set	Document No	
		Page	3/3
		Version	A/2

All raw materials used are non toxic, food and medical certified, as per European and FDA (USA) directives.

Shelf life

Three years from manufacturing date.

Storage

Store needles under room temperature and room well ventilated and without corrosive gas.

Shipping Information

Normal shipping; Normal dry container













Sterilization

The needle is sterilized by Ethylene Oxide, sterile, non-toxic, non-pyrogenic, non-hemolytic reaction.

Disposal modality

Before the use the products are to be considered not hazardous material. After the use become medical waste potentially infected that have to be collect and disposed applying all particular precautions to avoid infections

Information on the label and symbols

Symbol and Mark Key			
	Single Use		Latex Free
	Expiry Date		Catalog Number
	Batch Code		Keep Away from Sunlight
	Sterile		Manufacturer
	Authorized Representative		Consult Instructions for Use
	Method of Sterilization (ethylene oxide)		Date of Manufacture

General applicable directives

EU Quality Management System Certificate (MDR): Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

Standard Applied

EN ISO 13485:2016/AC:2018
 EN ISO 9626:2016
 EN ISO 11135:2014/A1:2019
 EN ISO 15223-1:2016
 EN ISO 10993-4:2017
 EN ISO 10993-10:2013
 ASTM F1980-16

EN ISO 14971:2019
 EN ISO 23908:2013
 EN ISO 11607-1:2020
 EN ISO 20417:2021
 EN ISO 10993-5:2009
 EN ISO 10993-11:2018

EN ISO 7864:2016
 EN ISO 80369-7:2017
 EN ISO 11607-2:2020
 EN ISO 10993-1:2020
 EN ISO 10993-7:2008/AC:2009
 ASTM D4169-16

Notified Body

TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
 NB Identification number: CE0123
 (EC) Certificate(s): No. G10 043324 0031 Rev. 00

	Product Technical Data IMPROSAFE Blood Collection Set	Document No	
		Page	4/3
		Version	A/2

Manufacturer

Guangzhou Improve Medical Instruments Co., Ltd.

No.102, Kaiyuan Avenue Science City Guangzhou Economic & Technological Development District 510530

Guangzhou, PEOPLE'S REPUBLIC OF CHINA

CE 0123