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Product Technical Data

Product Name IMPROSAFE[®] Blood Collection Set with pre-attached holder

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
IMPROSAFE Blood Collection Set with Pre-attached Holder				
596121192	Blood Collection Set with Pre-attached Holder	21G*3/4*7"	Green	50/500
596121302	Blood Collection Set with Pre-attached Holder	21G*3/4*12"	Green	50/500
596123192	Blood Collection Set with Pre-attached Holder	23G*3/4*7"	Blue	50/500
596123302	Blood Collection Set with Pre-attached Holder	23G*3/4*12"	Blue	50/500
596125192	Blood Collection Set with Pre-attached Holder	25G*3/4*7"	Orange	50/500
596125302	Blood Collection Set with Pre-attached Holder	25G*3/4*12"	Orange	50/500

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

Subject and application

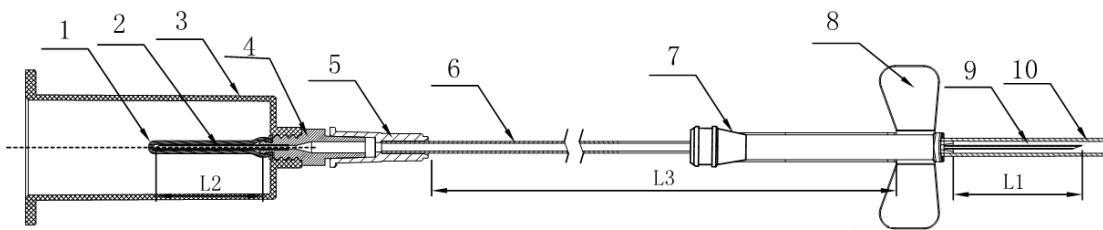
The products and evacuated blood collection tube/ syringe are used together for the collection of venous blood. The products are single-use, sterile, and non-pyrogenic.

Products	Accessories	
	Safety Shield	Needle Holder
IMPROSAFE [®] Blood Collection Set with pre-attached holder	YES	YES

Product photo



Structure and raw material




- 1—rubber sleeve: synthetic rubber
- 2—tube needle: Stainless steel
- 3—needle holder: Polypropylene (PP)
- 4—hub: acrylonitrile butadiene styrene (ABS)
- 5—luer adapter: PCTG
- 6—tubing: Polyvinyl Chloride (PVC)/ PVC with latex free & plasticizer free
- 7—safety shield: polypropylene (PP)
- 8—butterfly: Polyvinyl Chloride (PVC)
- 9—vein needle: Stainless steel
- 10—vein needle cover: polypropylene (PP)
- L1—vein needle length L2—tube needle length L3—tubing Length

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

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	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

Needle length, needle bevel angle

Type	Needle Nominal ID length L(mm)	Limit deviation (mm)	Bevel angle a	Note
Vein end needle	L<25	+1 -2	Short Bevel angle 17°±2° Long Bevel angle 11°±2°	
	25≤L<40	+1.5 -2.5		
	L=40	0 -4		
	L>40	+1.5 -2.5		
Tube end needle	L=23.4/24.5/25.7	+0.3 -0.3		

Prime volume

Priming 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

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













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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 14971:2019	EN ISO 7864:2016
EN ISO 9626:2016	EN ISO 23908:2013	EN ISO 80369-7:2017
EN ISO 11135:2014/A1:2019	EN ISO 11607-1:2020	EN ISO 11607-2:2020
EN ISO 15223-1:2016	EN ISO 20417:2021	EN ISO 10993-1:2020
EN ISO 10993-4:2017	EN ISO 10993-5:2009	EN ISO 10993-7:2008/AC:2009
EN ISO 10993-10:2013	EN ISO 10993-11:2018	ASTM D4169-16
ASTM F1980-16		

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

Manufacturer

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