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Product Technical Data

Product Name IMPROSAFE[®] Multisample needle with preattached holder

Item Code, specification, color code and package information

Product Code	Description	Needle Gauge * Needle Length(Inches) * Tubing Length(Inches)	Wing Col- or/shield color	Box/Carton Qty
IMPROSAFE Multi-sample Needle(WITH PREATTACHED HOLDER)				
598120380	Multi-sample Needle	20G*1½”	Yellow	50/500
598120250	Multi-sample Needle	20G*1”	Yellow	50/500
598121380	Multi-sample Needle	21G*1½”	Green	50/500
598121250	Multi-sample Needle	21G*1”	Green	50/500
598122380	Multi-sample Needle	22G*1½”	Black	50/500
598122250	Multi-sample Needle	22G*1”	Black	50/500
598123380	Multi-sample Needle	23G*1½”	Blue	50/500
598123250	Multi-sample Needle	23G*1”	Blue	50/500

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

Subject and application

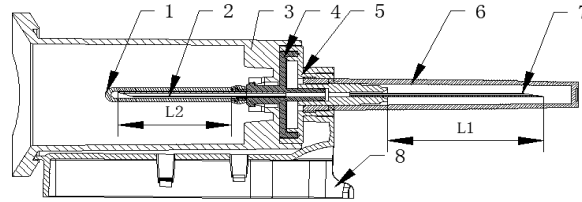
The products and evacuated blood collection tube are used together for the collection of venous blood. The products are designed with a safety shield which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needle stick injury. The 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 flashback cavity is designed to sign a venipuncture success. It also helps to add reassurance of flashback for the confidence of success.

The products are single-use, sterile, non-pyrogenic.

Product photo



Structure and raw material



- 1—rubber sleeve- nature/isoprene synthetic rubber
- 2—tube needle- Stainless steel
- 3—safety holder- polypropylene
- 4—tube needle hub-acrylonitrile butadiene styrene
- 5—vein needle hub - acrylonitrile butadiene styrene
- 6—vein needle cover - polypropylene
- 7—vein needle- Stainless steel
- 8—safety shield- 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

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°	
	25≤L<40	+1.5 -2.5		
	L=40	0 -4	Long Bevel angle	

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	L > 40	+1.5 -2.5	11°±2°	
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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











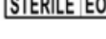

Sterilization

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

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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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