

 Product Technical Data Multi-sample Needle	Document No	
	Page	1/3
	Version	A/0

Product Technical Data

Product Name IMPROVACUTER[®] Multi -sample Needle

Item Code, specification, color code and package information

Product Code	Description	Needle Gauge * Length(Inches) * Needle Tubing Length(Inches)	Wing Color Color/shield	Box/Carton Qty
IMPROVACUTER Multi-sample Needle				
592118380	Multi-sample Needle	18G*1½"	Pink	100/4000
592118250	Multi-sample Needle	18G*1"	Pink	100/4000
592120380	Multi-sample Needle	20G*1½"	Yellow	100/4000
592120250	Multi-sample Needle	20G*1"	Yellow	100/4000
592121380	Multi-sample Needle	21G*1½"	Green	100/4000
592121250	Multi-sample Needle	21G*1"	Green	100/4000
592122380	Multi-sample Needle	22G*1½"	Black	100/4000
592122250	Multi-sample Needle	22G*1"	Black	100/4000
592123380	Multi-sample Needle	23G*1½"	Blue	100/4000
592123250	Multi-sample Needle	23G*1"	Blue	100/4000

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

Subject and application

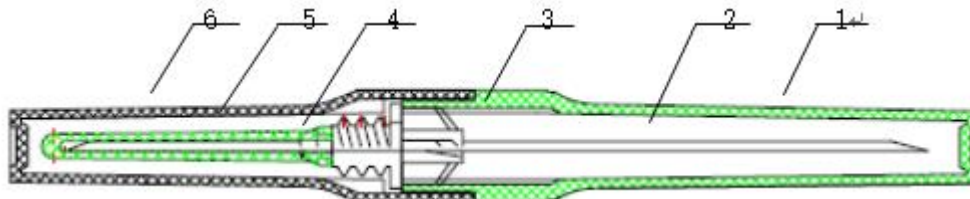
The products and evacuated blood collection tube/ syringe are used together for the collection of venous blood. The products are single-use, sterile, and non-pyrogenic.

Products	Accessories	
	Safety Shield	Needle Holder
IMPROVACUTER [®] Multi sample Needle	NO	NO

Product photo



Structure and raw material



1. Vein needle cover: polyolefin plastic
2. Vein puncture needle: Stainless steel
3. Needle hub: acrylonitrile butadiene styrene
4. Tube puncture needle: Stainless steel
5. Rubber sleeve: CIS-natural/isoprene synthetic rubber
6. Tube needle cover: polyolefin plastic

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

Raw material certifications

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

Shelf life

Five years from manufacturing date.

Storage

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

	Product Technical Data Multi-sample Needle	Document No	
		Page	3/3
		Version	A/0

Shipping Information

Normal shipping; Normal dry container

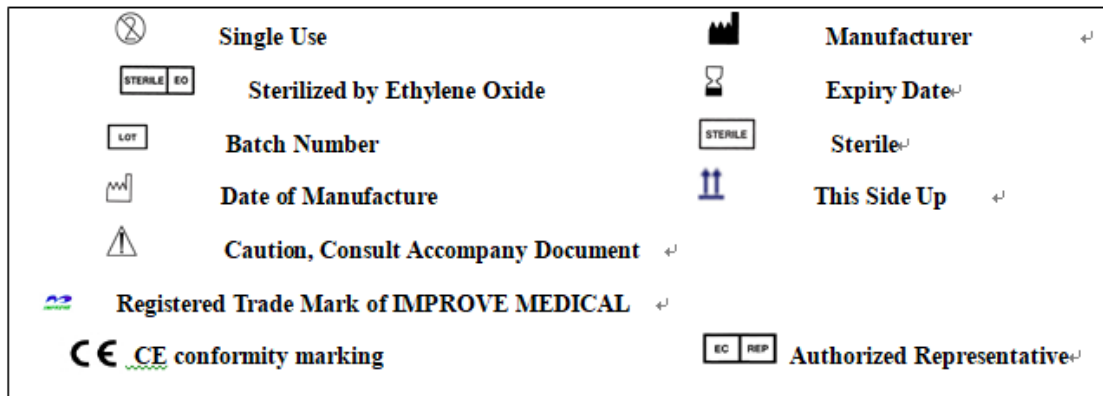
Sterilization

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



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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