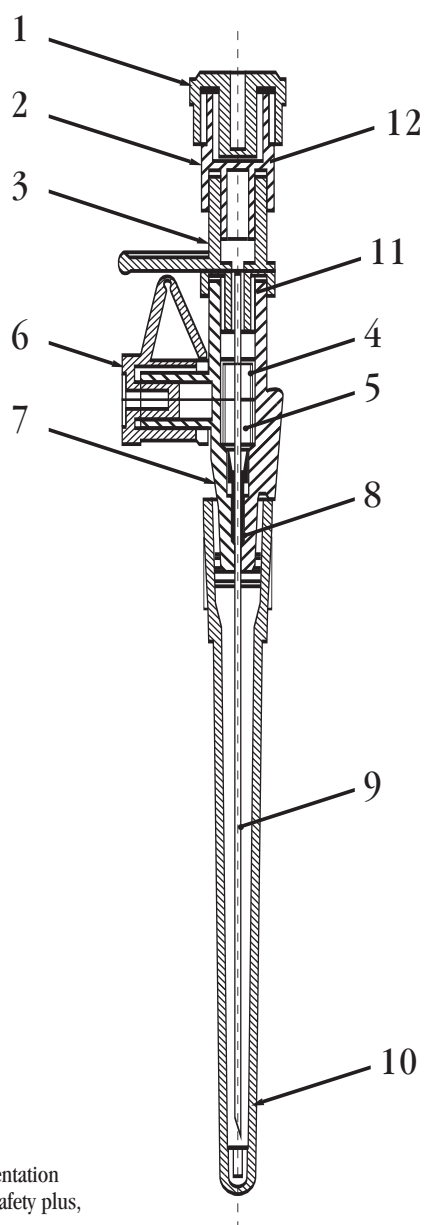




Technical Data sheet **TRO-VENSITE safety plus, Safety I.V. Cannula**
sterile, Luer lock, with port, with wings, FEP or PUR Catheter



Technical Data sheet **TRO-VENSITE safety plus**

1. Luer Lock Plug
2. Flash back chamber
3. Needle Hub
4. Silicone Tube
5. Cannula
6. Injection port with cap
7. Wing Housing
8. Slip Ring
9. Catheter
10. Needle Cover
11. Position of safety clip
12. Position of hydrophobic filter

Figura 1
Schematic representation
of TRO-VENSITE safety plus,
Safety I.V. Cannula

Quality: DIN EN ISO 10555-5

Material: FEP or PUR Catheter

Shelf life: 5 years



0044

STERILE EO

EN ISO 9001
EN ISO 13485
CERTIFIED

NOTE The drawing is intended to be illustrative of components of a Safety I.V. Cannula.

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TECHNICAL DATA SHEET

TROGE MEDICAL GMBH

Ref. Nos:

90220 | 90221 | 90222 | 90223 | 90224 | 90225 | 90226 | 90227 | 90228
90250 | 90251 | 90252 | 90253 | 90254 | 90255 | 90256 | 90257 | 90258

TRO-VEN SITE safety plus, Safety I.V. Cannula **sterile, Luer lock, with injection port, with wings, latex free, Teflon® (FEP) or Polyurethane Catheter**

Product:		Safety I.V. Cannula	
Product description:		The TRO-VEN SITE safety , Safety I.V. cannula consisting of flexible plastic material is virtually non thrombogenic and is available in different types as desired. Thanks to the special safety clip which automatically covers the needle tip after withdrawal needle stick injuries and reuse are avoided. It can be safely and easily affixed to the skin with its two movable wings. With hydrophobic filter, pyrogen-free and atoxic.	
Components		Material/Characteristics	International standard
1.	Luer Lock Plug	HDPE	DIN EN 20594 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment
2.	Flash Back Chamber	Polypropylene	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
3.	Needle Hub	Polypropylene	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
4.	Silicone Tube	Silicone	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
5.	Cannula	Stainless steel	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
6.	Port Cap	Polypropylene (HD + LD)	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
7.	Wing Housing	Polypropylene	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
8.	Slip Ring	Polyacetal	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
9.	Safety Clip	Polycarbonate	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
10.	Catheter	Teflon (FEP) or Polyurethane (PUR)	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
11.	Needle cover	Polyethylene (HD + LD)	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters



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Components	Material/Characteristics	International standards
Box	Pieces per box: 50 pieces	
Export Carton	10 boxes of 50 pieces Measurements: 69x33x19 cm	
Unit Packing	Individual packed in a "Tyvek-blister"	DIN EN 868 Packaging materials and systems for medical devices which are to be sterilized - Part 2: Sterilization wrap; requirements and test method
Product Quality	CE 0044	DIN EN ISO 10555-5 Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters
Product class	Ila	Classification according to Annex IX of directive 93/42EEC on Medical devices
Shelf life	5 years	
Sterility and Cycle Validation	EO-sterile	EN 550 Validation and observation for sterilization with Ethylene Oxide (DIN EN ISO 11135-1)
Pyrogens	Pyrogen-free	USP 28, EP 4th edition
Biological Safety	No haemolytic, cytotoxic effects	DIN EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing
Product Safety	No potential risk for user and patient when used in accordance with the IFU and for the intended purposes	DIN EN ISO 14971 Medical devices - Application of risk management to medical devices
Quality control	According to written procedures	DIN EN ISO 13485 Medical devices - Quality management systems—Guidance on the application of ISO 13485:2003
	To quality System Manual	DIN EN ISO 9001 Quality management systems -Requirements



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TECHNICAL DATA SHEET

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- Measurements –

Components		
Luer lock plug	Diameter [mm]	10,20 ± 0,01
	Height [mm]	10,00 ± 0,01
Flash back chamber	Length [mm]	16,80 ± 0,01
	Diameter [mm]	7,00 ± 0,01
Needle Hub	Length [mm]	17,00 ± 0,01
	Diameter [mm]	6,00 ± 0,01
Port Cap	Height [mm]	8,47 ± 0,01
	Diameter [mm]	10,44 ± 0,01
Silicone Tube	Length [mm]	9,0 ± 0,1
	External Diameter [mm]	3,85 ± 0,01
	Internal Diameter [mm]	2,70 ± 0,01
Wing Housing	Width of the wings [mm]	29,88 ± 0,01
	Length [mm]	32,20 ± 0,01
Slip Ring	Length [mm]	9,50 ± 0,01
	Diameter [mm]	1,90 ± 0,01
Safety Clip	Length [mm]	11,5 ± 0,05
	Diameter [mm]	3,70 ± 0,02

- Catheter -

Ref.Nos.: (FEP)	(PUR)	Measurements	Colour code	External Diameter [mm]	Length [mm]
90250	90220	14G	Orange	2,0	45
90251	90221	16G	Grey	1,7	45
90252	90222	17G	White	1,5	45
90254	90223	18G	Green	1,3	45
90253	90224	18G	Green	1,3	32
90255	90225	20G	Pink	1,1	32
90256	90226	22G	Blue	0,9	25
90257	90227	24G	Yellow	0,7	19
90258	90228	26G	Violet	0,6	19

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Hamburg, 05/2010

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