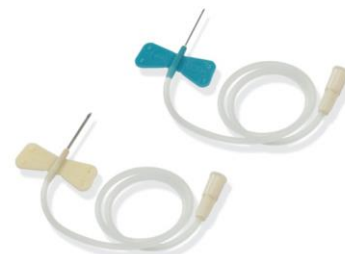


PRODUCT DATA SHEET
WINGED NEEDLE SET – DEHP FREE

Reference Items	Description
REF:	PSV- XX- ET
Associated group	Infusion Systems
Product description	Winged needle set (Scalp vein set)
Intended use	Infusion therapy



Reference code	Description	Tubing length	Purpose	Flow rate not less than (ml/min)	Colour code (wing hub)	Priming volume
PSV-18-ET	Scalp Vein set 18Gx3/4" (1.2x19mm)	300 mm	IV/ SC	46.5 ml/min		0.46ml
PSV-19-ET	Scalp Vein set 19Gx3/4" (1.1x19mm)	300 mm	IV/ SC	36.5 ml/min		0.47ml
PSV-20-ET	Scalp Vein set 20Gx3/4" (0.9x19mm)	300 mm	IV/ SC	25.8 ml/min		0.45ml
PSV-21-ET	Scalp Vein set 21Gx3/4" (0.8x19mm)	300 mm	IV/ SC	20 ml/min		0.44ml
PSV-22-ET	Scalp Vein set 22Gx3/4" (0.7x19mm)	300 mm	IV/ SC	12 ml/min		0.44ml
PSV-23-ET	Scalp Vein set 23Gx3/4" (0.6x19mm)	300 mm	IV/ SC	7.8 ml/min		0.44ml
PSV-25-ET	Scalp Vein set 25Gx3/4" (0.5x19mm)	300 mm	IV/ SC	3.7 ml/min		0.44ml
PSV-27-ET	Scalp Vein set 27Gx3/4" (0.4x19mm)	300 mm	IV/ SC	0.35 ml/min		0.44ml

SC: Sub cutaneous I.V. Intravenous

Product Registrations	
CE- marked	CE
Classification	Medical Devices
Medical Product class	Class II a
Rule	Rule 7
Guideline	MDD 93/ 42/ EEC
UMDNS	12752

PRODUCT DATA SHEET

Standard norms:

ISO 15223-1/ ISO 11607-1/ ISO 11607-2/ EN ISO 9001
EN ISO 13485/ISO 7864/ EN 1707/ ISO 594-1/ ISO 594-2/ISO 6009

Manufacturing details

Legal Manufacturer	Nipro Corporation
Country of origin	THAILAND

Product materials

All materials used to produce our scalp vein set are medical grade and latex-free and DEHP-Free.

Polypropylene	PSV protector, Luer cap, luer adapter
Silicone	Siliconization on lancet point tip
ABS (Acrylonitril-Butadien-Styreen)	Luer connector
PVC (Polyvinylchloride)	Wing hub, PSV tube
Epoxy (Resin)	Glue
Stainless steel	Type SUS-304 : Needle (= cannula)
Cutting angles	Three-beveled: minimize pain to the patient and damage to the blood vessel.

Product Sterilization

Sterile	ETO Sterilization procedure Ethylene – Oxide	
Do NOT re-use	Single use only	

Each outer box (or shipping carton) contains a chemical indicator, which ensures sterility. This indicator is a blue sticker, which turns red when sterilized.

PRODUCT DATA SHEET

Packaging

- LOT-number
- Expiry : 5 years 
- REF: PSV-XX-ET
- QTY- pieces
- Barcode

Example of Label:

PRODUCT NAME		PRODUCT DESCRIPTION/SIZE	
REF : PRODUCT REFERENCE	BOX QUANTITY		
Barcode GTIN-13 5 420040 825008		LOT : LOT NUMBER	USE BY DATE
Barcode GTIN-14 (01)25420040825002(17)131000(30)50(10)08K28H			

An individual package, blister type contains one set of scalp vein set.

Transport conditions

Closed and dry

Storage conditions

Only open the packaging before use to guarantee sterility.

Reference	Gauge (needle size)	Length (mm)	Quantity inner box	Quantity Outer box	Net Weight (g)	Gross Weight (kg)	INNER BOX			OUTER BOX			M ³
							L mm	W mm	H mm	L mm	W mm	H mm	
PSV-18-ET	18	19	50	1000	6,100	7,100	247	110	78	572	264	344	0,052
PSV-19-ET	19	19	50	1000	6,100	7,100	247	110	78	572	264	344	0,052
PSV-20-ET	20	19	50	1000	6,100	7,100	247	110	78	572	264	344	0,052
PSV-21-ET	21	19	50	1000	5,400	6,400	247	110	78	572	264	344	0,052
PSV-22-ET	22	19	50	1000	6,100	7,100	247	110	78	572	264	344	0,052
PSV-23-ET	23	19	50	1000	6,100	7,100	247	110	78	572	264	344	0,052
PSV-25-ET	25	19	50	1000	6,100	7,100	247	110	78	572	264	344	0,052
PSV-27-ET	27	19	50	1000	6,100	7,100	247	110	78	572	264	344	0,052

12 Languages on packaging according the specifications of European Medical Device Directive:

- English, French, Dutch, German, Spanish, Italian, Portuguese, Greek, Swedish, Danish, Norwegian, Finnish



Contact details

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