

SPECIFICATIONS

ROMED DISPOSABLE SCALP VEIN SET

REF: 18G/19G/20G/21G/22G/23G/24G/25G



Medical device conform MDD 93/42/EEC

Scalp vein sets are designed to provide rapid venous access with greater patient comfort during infusion. Short bevelled siliconized needle facilitates atraumatic cannulation. Thin wall needle provides better flow rate per gauge, as in the same cannula more circumference is available for better flow of fluid. Butterfly shaped wings facilitate easy handling and attachment with the skin. Butterflies are colour coded for instant identification of needle size. Butterfly is connected to soft non-toxic, non-irritant, medical grade tube, which does not kink.

MATERIALS

Part	Raw material	
1. Safety cover	Polypropylene	PP
2. Cannula	Stainless Steel	Cr18Ni9Ti
3. Butterfly wings	Polyvinyl Chloride	PVC
4. Tube ϕ 4x3	Polyvinyl Chloride	PVC
5. Luer Lok connector	Polyvinyl Chloride	PVC
6. Cap for Luer Lok	Polyethylene	PE

Scalp vein sets contain phthalates (DEHP)

DIMENSIONS

Gauge	Metric system	Tube length	Colour	Ref
18Gx3/4"	1.20x19 mm	30 cm	pink	18G
19Gx3/4"	1.05x19 mm	30 cm	white	19G
20Gx3/4"	0.90x19 mm	30 cm	yellow	20G
21Gx3/4"	0.80x19 mm	30 cm	green	21G
22Gx3/4"	0.70x19 mm	30 cm	black	22G
23Gx3/4"	0.60x19 mm	30 cm	light blue	23G
24Gx3/4"	0.55x19 mm	30 cm	violet	24G
25Gx3/4"	0.50x19 mm	30 cm	orange	25G

VAN OOSTVEEN MEDICAL B.V. – ROMED HOLLAND, Herenweg 269, 3648 CH Wilnis, NL

www.romed.nl Tel.: +31 0297 282101, fax: +31 0297 288316, e-mail: info@romed.nl

2019-06

PROPERTIES

Terms	Requirements											
Physical												
Surface finish and visual appearance	When examined by normal or corrected vision, the outside surface of the tubing shall be smooth and free from defects											
Cleanliness	When examined by normal or corrected vision, the surface of the tubing shall be free from metal soil and processing agents											
Colour Coding	the designated metric size of scalp vein set shall be identified by colour coding in accordance with ISO6009 applied to the unit packing and /or part of scalp vein set assembly such as hub or handler											
Particulate Contamination	the contamination index limit≤90											
Tensile Strength	bond between handler and needle tube shall withstand a static tensile force of not less than 20N for 15 S											
	bond between cannula and other parts shall withstand a static tensile force of not less than15N for 10 S											
Leakage	Immerse into water(20°C-30°C),inflating through connector, keep no less than 50 kPa 10s. There should be no signs of leakage.											
Flow Rate	Under 20kpa pressure the flow rate no less than the table											
	size	28G	27G	26G	25G	24G	23G	22G	21G	20G	19G	18G
	Flow rate ML/MIN	2.0	2.5	2.8	3.2	3.8	5.0	11.0	21.0	36.0	48.0	48.0
Needle Tube Length	≤15mm +/- 0.1mm > 15mm +1.5/-2.0mm											
Needle Tip	Sharp, no raw edge and burr											
Cannula	Soft, transparent, easy to observe the air bubbles											
Protective caps	Easy remove											
Chemical												
Reducing matter	No more than 2.0ml of kmno4											
Titration acidity or Alkalinity	No more than cost 1ml for drip liquid											
Absorption	(250nm-320nm) no more than 0.1											
EO residue	No more than 0.5mg each piece											
Biological												
Sterility	Sterile											
Endotoxin	No more than 20EU for each piece											

STERILIZATION

Sterilised by ethylene oxide gas

Expiry date: 5 years after sterilisation

PACKING

Per piece in a peel pouch, 100 pieces in an inner box, 1000 pieces in an export carton

VAN OOSTVEEN MEDICAL B.V. – ROMED HOLLAND, Herenweg 269, 3648 CH Wilnis, NL

www.romed.nl Tel.: +31 0297 282101, fax: +31 0297 288316, e-mail: info@romed.nl

2019-06