

STERILE QUINCKE SPINAL NEEDLES WITHOUT INTRODUCER TECHNICAL INFORMATION

Definition

- Spinal needle with non-traumatic Quincke tip to ensure immediate closure of injection point and reduce the loss of C.S. F. Sterile disposable, pyrogen free, non-toxic.



General features

- Transparent Luer Lock hub.
- Individual "Peel-Open" blister.
- Non-traumatic Quincke type sharpening.
- International color coded.
- With mandrel.



Applications

- Subdural, lower thoracic and lumbar spinal injection.

Medical device according to the directive CEE 93/42
Modified by the directive 2007/47/CE
Implementation with D.L. n°37 del 25-01-2010

Class III

Conformity

- ISO 9626 tubes for medical instrument
- ISO 6009 Codification of identification's colours
- ISO 2859 Sampling plan
- ISO 11135 Sterilization
- ISO 10993 Biocompatibility
- Quality Assurance system: certified according to ISO 9001
- Quality Assurance system: certified according to ISO 13485



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Technical specifications

COMPONENT	MATERIAL	CONFORMITY
Needle hub	Polycarbonate non-toxic	Directive 10/2011 CEE
Mandrel hub	Polypropylene non-toxic	Directive 10/2011 CEE
Canula	Stainless steel AISI 304	ISO 9626
Mandrel	Stainless steel AISI 304	ISO 9626
Shield	Polyethylene non-toxic	Directive 10/2011 CEE
Glue	Epoxy, non-toxic glue	Directive 10/2011 CEE
Colourant		D.M. 21-03-73 and following modifications

Sterile	YES
Latex	NO
Phtalate	NO
Expiry date	5 years from the production date in not damaged pack
Storage instructions	Store in a cool, dry place away from chemical substances

Product sterilization

- Gas Ethylene Oxide according to norm ISO 11135

Biocompatibility

- The product has successfully undergone the biocompatibility tests required by ISO 10993, for cytotoxicity, emocompatibility, sensitization, toxicity and skin reactivity test

Disposal

- In compliance with applicable laws

Productive process

- Integrated areas of high automation in CLEAN ROOMS of class 100.000 (ISO 8)

Quality control

- Quality controls in process 100% and with sampling plan according to ISO 2859 norm

Packaging

Labels and/or packages have the following:

Product definition
CE Mark
Dimension
Manufacturer
Method of sterilization
Expiry date
Storage instructions
Product Bar code
Batch Bar code

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PIKDARE

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Pikdare S.r.l. - Via Saldarini Catelli 10 - 22070 Casnate con Bernate (CO) - Italy

Tel. 0039 031 7297111 - Fax 0039 031 7297100 - www.picsolution.com



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Packaging material

Component	Material	Conformity
Single blister	Medical paper	F.D.A. (section 21-CFR176-170)
	Plastic film in PE+PP	D.M. 21-03-73 and following modifications
Box	Patterned cardboard	G.I.F.C.O.
Package	Corrugated paper	G.I.F.C.O.

Manufacturer

➤ Pikkare S.r.l Via Saldarini Catelli 10, 22070 Casnate con Bernate Como - Italy

Assortment

CODE	COLOUR	GAUGE	MM	BOX	CARTON
Without introducer					
02044018300000	Rose	18x3"	1,20x75	30 pcs	600 pcs
02044018400000	Rose	18x3 1/2"	1,20x90	30 pcs	600 pcs
02044019400000	Amber	19x3 1/2"	1,10x90	30 pcs	600 pcs
02044020300000	Yellow	20x3"	0,90x75	30 pcs	600 pcs
02044020400000	Yellow	20x3 1/2"	0,90x90	30 pcs	600 pcs
02044021400000	Green	21x3 1/2"	0,80x90	30 pcs	600 pcs
02044022300000	Black	22x3"	0,70x75	30 pcs	600 pcs
02044022200000	Black	22x1 1/2"	0,70x40	30 pcs	600 pcs
02044022400000	Black	22x3 1/2"	0,70x90	30 pcs	600 pcs
02044023300000	Blue	23x3"	0,60x75	30 pcs	600 pcs
02044023400000	Blue	23x3 1/2"	0,60x90	30 pcs	600 pcs
02044025300000	Orange	25x3"	0,50x75	30 pcs	600 pcs
02044025400000	Orange	25x3 1/2"	0,50x90	30 pcs	600 pcs
02044026400000	Hazelnut	26x3 1/2"	0,45x90	30 pcs	600 pcs
02044027400000	grey	27x3 1/2"	0,40x90	30 pcs	600 pcs

Technical director

PIKDARE S.R.L.
Dr. MAURO CASSANI
Medical Devices Department
Technical Director

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