

"QUINCKE" BEVEL		
REF	Gauge x length (in)	Hub Color
26960	18G x 3-1/2"	Pink
26962**	16G x 3-1/2"	White
26963**	20G x 1-1/2"	Yellow
26964	20G x 3-1/2"	Yellow
26965	22G x 2-3/4"	Black
26966**	22G x 1-1/2"	Black
26967*	22G x 3-1/2"	Black
26968	23G x 3-1/2"	Deep Blue
26969*	27G x 3-1/2"	Medium Gray
26970	25G x 3-1/2"	Orange
26971	21G x 3-1/2"	Deep Green
26972	24G x 3-1/2"	Purple
26973**	26G x 3-1/2"	Brown

\* model not marketed in Australia or New Zealand  
 \*\* model not marketed in EU, Australia, or New Zealand



**Instructions For Use (IFU)**

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- 1 Device Description
  - 1.1 Sterile, Single Use, Spinal Needle with Quincke Bevel or Whitacre Pencil Point is designed for spinal anesthesia.
- 2 Intended Use
  - 2.1 The intended use of the Spinal Needle is to inject anesthetics into spine or extract spinal fluid from spine after puncturing the patient's skin or tissue.

**3 Indications for Use/Target Users**

- 3.1 The spinal needle is indicated for the injection of anesthesia or the extraction of spinal fluid.
- 3.2 The device is designed for use by a qualified physician or clinician.
- 3.3 The spinal needles are indicated for use with the general patient population.

**4 Benefits of Use**

- 4.1 Safe, easy to use.
- 4.2 Siliconized for smooth comfortable penetration.
- 4.3 Transparent plastic hub.
- 4.4 Each device is individually packaged, sterilized and ready for use.

**5 Warnings/Precautions**

- 5.1 Read instructions for use.
- 5.2 Always check the integrity of product, packaging, and expiration date before use.
- 5.3 Use product immediately after opening.
- 5.4 For single-patient-use only. Use once and destroy.
- 5.5 Reuse of the device can result in contamination or transmit disease.
- 5.6 The sterility of each needle is guaranteed until opened or damaged.

U.S Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

**6 Contraindications**

- 6.1 There are no recognized contraindications for the use of Spinal Needles.

**7 Sterility**

- 7.1 Spinal Needles are sterilized by Ethylene Oxide (EtO) gas sterilization (indicated by for single use only.
- 7.2 Do not re-use.
- 7.3 Do not re-sterilize.
- 7.4 Inspect each package prior to use. Do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened the device must be used or discarded.

## 8 Operating Instructions

- 8.1 Twist the needle cap to break the seal using proper sterile technique.
- 8.2 Check the needle tip and needle body to ensure there is no damage and the needle stiletto is moving easily.
- 8.3 Adapt the needles to the operation surface by using plastic piece located in the package.
- 8.4 Use standard aseptic technique to puncture the skin surface.
- 8.5 Move into the subarachnoidal area from the specified point. Be sure, the needle tip is at subarachnoidal area by pulling the stiletto back. With that way, you can check the BOS flow.
- 8.6 After the assurance of the needle tip is inserted to the subarachnoidal area, please remove the stiletto and inject the anesthetic material.
- 8.7 After procedure is completed, remove the needle by pulling it back.
- 8.8 Dispose of the needle in compliance with the local regulatory requirements of handling medical waste.

## 9 Storage

- 9.1 Store at room temperature 1°C-35°C.
- 9.2 Do not store in high temperatures and humidity.
- 9.3 Keep away from direct sunlight.
- 9.4 Keep away from rain.
- 9.5 Store in a cool and dry place.

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	<b>EXELINT International, Co.</b> 2500 Santa Fe Avenue, Redondo Beach, CA 90278 U.S.A. Tel: (310) 649-0707 Fax: (310) 649-1178 e-mail: <a href="mailto:info@exelmed.com">info@exelmed.com</a>
	FOR U.S.A. INFO CALL: 800-940-3935 <a href="http://www.exelint.com">www.exelint.com</a> e-mail: <a href="mailto:info@exelint.com">info@exelint.com</a>
 	<b>EMERGO EUROPE</b> Westervoortsedijk 60 6827 AT, Arnhem The Netherlands
	<b>Emergo Australia</b> Level 20 Tower II Darling Park 201 Sussex Street Sydney, NSW 2000 Australia

### Graphic Symbol Legend for Medical Device Labeling

	Medical Device
	Catalog number
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Consult instructions for use
	Important Cautionary Information
	Sterilized by Ethylene Oxide. Sterility guaranteed if package unopened and undamaged.
	Manufacturer's Lot Number
	Unique Device Identifier
	Use by
	Country of Manufacture
	For single-patient-use only. Do not reuse.
	Do not use if package is damaged
	Keep away from sunlight
	Keep Dry
	Temperature Limit
	Non-Pyrogenic
	Single Sterile Barrier
	This device is not manufactured with Natural Rubber Latex
	Manufacturer
	Product marketed in European countries
	European Representative
	Australian Sponsor