OVER 25 YEARS
OF INDUSTRY LEADERSHIP
IN THE DESIGN AND MANUFACTURING OF PRECISION MEDICAL DEVICES

SPECTRA®
ESTABLISHED IN 1995
LEADING EDGE MEDICAL DEVICES

Sodium Chloride Injection, USP, 0.9%, 5 mL and 10 mL, Single-Dose Ampules

- Sodium Chloride Injection, USP, 0.9%
- Glass Ampules
- Preservative Free
- Manufactured for Spectra Medical Devices, LLC., Wilmington, MA 01887 by Huons Co., Ltd., Seoul, South Korea

How To Order:
5 mL Single-Dose Glass Ampules*
Box of 25 / Carton of 900
NDC: 65282-1505-1

10 mL Single-Dose Glass Ampules*
Box of 25 / Carton of 600
NDC: 65282-1510-1

**USP Type 1 Glass Ampules, hermetically sealed, compatible with EtO sterilization.*

IMPORTANT SAFETY INFORMATION

PRECAUTIONS

- Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.
- Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.
- Pregnancy Category C - Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Injection, USP. It is also not known whether sodium chloride injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride injection containing additives should be given to a pregnant woman only if clearly needed.
- Pediatric Use - The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

DRUG INTERACTIONS

- Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol.
- Use aseptic technique for single or multiple entry and withdrawal from all containers.
- When diluting or dissolving drugs, mix thoroughly and use promptly.
- Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.
- Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers, discard unused portion.

ADVERSE REACTIONS

- Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.
- If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE

- Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of carbohydrate, sodium chloride or fluid overload except possibly in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures.

Please refer to full Prescribing Information found at www.spectramedical.com.

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Wilmington, MA 01887 | 978-657-0889 | sales@spectramedical.com | www.spectramedical.com

SMD-Brochure-0026 rev. 002

SPECTRA®
ESTABLISHED IN 1995
LEADING EDGE MEDICAL DEVICES

LEADING EDGE PRODUCTS FOR PAIN MANAGEMENT

SPECTRA MEDICAL DEVICES, LLC.
A GLOBAL SOURCE
FOR ADVANCED PAIN MANAGEMENT SOLUTIONS

Spectra has been manufacturing state-of-the-art procedural needles that facilitate and advance pain management treatment for over 25 years. Spectra is also an FDA-approved source for Lidocaine ampules and vials, Sodium Chloride ampules and Bupivacaine ampules. Our corporate commitment to the highest quality, reliability, patient safety and availability have made Spectra a world class manufacturer of pain management products.

Spectra's advanced designs, unsurpassed precision, custom configurations and reputation for superior quality and reliable pain management products are preferred by health care providers, patients, medical suppliers and procedural kit manufacturers around the world today.

Intertek

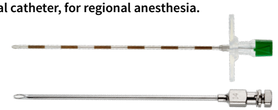
For more information or to order, please email sales@spectramedical.com or call 978-657-0889.

YOUR SINGLE SOURCE FOR A FULL LINE OF ADVANCED PAIN MANAGEMENT SOLUTIONS

Discover Spectra's full line of customizable pain management products varying in style, length, gauge, and applications, as well as pain management prescription drugs manufactured for Spectra's distribution.

Epidural Needles | Plastic or Metal Hub

Use in pain management, for introducing an epidural catheter, for regional anesthesia.



- 510(k) clearance | CE 0413 marking
- ISO 80369-6 (NRFit®) compliant hubs
- Cath Slide® process ensures unscathed catheter advancement and retraction
- Epi-Match® technology
- With or without cm depth markings
- Tuohy, Hustead, Crawford or Weiss styles
- Customizable Sharpness Regular/Dull/Super Dull

Sizes: 14GA - 25GA
Lengths: 2"- 6"
(custom sizes available upon request)

Peripheral Nerve Block (PNB) - Continuous

The ultrasound visualization our echogenic PNB needles provide, make it easier for physicians to introduce their catheter, into the correct location.

- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant hubs
- Available with Spectra Guide™ dimpling for superior clarity
- Inner diameter unaffected by echogenic field so catheter advances smoothly
- Tuohy or Crawford styles

Sizes: 16GA - 25GA
Lengths: 1"- 7"
(custom sizes available upon request)

Spinal Cord Stimulation Lead Introducers

Internal and external edges are completely rounded by our proprietary Cath Glide® process, to reduce the changes of skiving, hanging up or damaging the spinal cord stimulator SCS lead, during introduction to the patient.

- ISO 80369-6 (NRFit®) compliant hubs
- Plastic or metal hub
- With or without calibration markings
- Curved or straight

Sizes: 13GA - 16GA
Lengths: 4"- 6.5"
(custom sizes available upon request)

Spinal Introducer Needles

Spinal introducer needles are designed to provide additional support for easy insertion and to maximize precise placement of the small-gauge spinal needle during spinal anesthesia.

- Aluminum, metal or plastic hub
- Knurled Hub
- Smooth transition for needle insertion and passage

Sizes: 19GA - 22GA
Lengths: 1" - 3.5"
(custom sizes available upon request)

Spectra will work with customers to generate drawings, specifications and R&D for custom small batches.
All products listed above are single use, disposable.

Spinal Needles

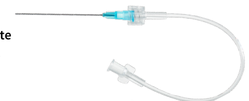
Spectra's spinal needles are offered in a full selection of needle styles and sizes for spinal anesthesia.

- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant hubs
- With or without cm depth markings
- Clear, plastic hub with color-coded stylet cap
- Optional bevel orientation indicators
- Spectra Guide™ and Block Glide® available
- Quincke, Chiba, Sprotte (Pencil Point) or Whitacre (Pencil Point) style

Sizes: 18GA - 27GA
Lengths: 1.5"- 12"
(custom sizes available upon request)

Peripheral Nerve Block (PNB) - Single Shot

Offers clear needle tip visualization for safe and accurate needle placement for ultrasound guided MSK injection.



- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant hubs
- Spectra Guide™ dimpling available for superior clarity
- Uses highest tensile 304 stainless steel
- Bevel orientation indicator ensures proper alignment

Sizes: 21GA - 23GA
Lengths: 2.5"- 6"
(custom sizes available upon request)

Echoshot™ Injection Needles

Spectra's Echoshot™ injection needles are disposable lubricated echogenic needles with fluid injection for joint injection peripheral nerve blocks and injection of radio contrast medium.

- Small ergonomic hub
- 30 cm integral tube and luer connector
- Spectra dimpled echogenic design for clear imaging
- For controlled steerable needle placement and injection

Sizes: 21GA - 23GA
Shaft Lengths: 6 - 15 cm
(custom sizes available upon request)

Radiofrequency (RF) Needles

For over 15 years, Spectra has been supplying the Pain Management field with millions of RF needles. We manufacture a wide variety of RF needles, offering the largest array of gauges, lengths, active tips, echogenic and lubricated needles in the market.

- 510(k) clearance | CE 0413 marking
- Quincke bevel or lancet bevel
- Straight, curved, blunt or sharp tip

Sizes: 16GA, 18GA, 20GA, 21GA, 22GA
Lengths: 5 cm, 10 cm, 15 cm, 20 cm
Active Tip Lengths: 4 mm, 5 mm, 10 mm, 15 mm, 20 mm
(custom sizes available upon request)

Loss of Resistance (LOR) Syringes

Spectra's Glass Loss of Resistance Syringes offer smooth, low friction consistent plunger movements when used in conjunction with an epidural needle, to assist in locating the epidural space.

- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant hubs
- Norprene® Shroud application prevents transit damages

Sizes:
Metal Luer Slip: 3 cc, 5 cc, 10 cc
Metal Luer Lock: 3 cc, 5 cc, 10 cc
Glass Luer Slip: 3 cc, 5 cc, 10 cc

Spectra will work with customers to generate drawings, specifications and R&D for custom small batches.
All products listed above are single use, disposable.

Lidocaine Hydrochloride Injection, USP, 1%, 5 mL Single-Dose Ampules/Single-Dose Vials

- Lidocaine Hydrochloride Injection, USP, 1%
- Glass Ampules / Glass Vials
- Preservative Free

How To Order:
5 mL Single-Dose Glass Ampules*
Box of 25 / Carton of 900
NDC: 65282-1605-1

**USP Type I Glass Ampules, hermetically sealed, compatible with EtO sterilization. Glass is impermeable to EtO per ANSI/AAMI ST41:1999 Standard*

How To Order:
5 mL Single-Dose Glass Vials
Box of 10 / Carton of 600
NDC: 73293-0001-1, 73293-0001-2

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

Lidocaine Hydrochloride Injection, USP is indicated for production of local or regional anesthesia by infiltration techniques such as percutaneous injection and intravenous regional anesthesia by peripheral nerve block techniques such as brachial plexus and intercostal and by central neural techniques such as lumbar and caudal epidural blocks, when the accepted procedures for these techniques as described in standard textbooks are observed.

IMPORTANT SAFETY INFORMATION

Lidocaine HCl is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

WARNINGS AND PRECAUTIONS

LIDOCAINE HYDROCHLORIDE INJECTION, USP FOR INFILTRATION AND NERVE BLOCK SHOULD BE EMPLOYED ONLY BY CLINICIANS WHO ARE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ACUTE EMERGENCIES THAT MIGHT ARISE FROM THE BLOCK TO BE EMPLOYED AND THEN ONLY AFTER ENSURING THE IMMEDIATE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY EQUIPMENT AND THE PERSONNEL NEEDED FOR PROPER MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES.

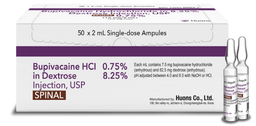
PROPER MANAGEMENT OF DOSE-RELATED TOXICITY, UNDERVENTILATION FROM ANY CAUSE AND/OR ALTERED SENSITIVITY MAY LEAD TO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST AND, POSSIBLY, DEATH.

- To avoid intravascular injection, aspiration should be performed before the local anesthetic solution is injected. The needle must be repositioned until no return of blood can be elicited by aspiration.
- In the case of severe reaction, discontinue the use of the drug.
- The safety and effectiveness of lidocaine HCl depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies.
- Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use.
- Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their age and physical condition. Lidocaine HCl should also be used with caution in patients with severe shock or heart block.
- Use with caution in patients with hepatic disease.
- Use with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs.
- The intramuscular injection of lidocaine HCl may result in an increase in creatine phosphokinase levels.

Please refer to full Prescribing Information found at www.spectramedical.com.

Bupivacaine Hydrochloride in Dextrose Injection, USP, 0.75%; 8.25%, 2 mL Single-Dose Ampules

- Bupivacaine HCL in Dextrose USP 0.75%/8.25%
- Glass Ampules
- Preservative Free



How To Order:
2 mL Single-Dose Glass Ampules*
Box of 50 / Carton of 2,000
NDC: 73293-0002-1, 73293-0002-2

**USP Type 1 Glass Ampules, hermetically sealed, compatible with EtO sterilization. Glass is impermeable to EtO per ANSI/AAMI ST41:1999 Standard*

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

Bupivacaine Hydrochloride in Dextrose Injection, USP is indicated for the production of subarachnoid block (spinal anesthesia).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

Bupivacaine Hydrochloride in Dextrose Injection, USP is contraindicated in patients with a known hypersensitivity to it or to any local anesthetic agent of the amide-type.

The following conditions preclude the use of spinal anesthesia:

1. Severe hemorrhage, severe hypotension or shock and arrhythmias, such as complete heart block, which severely restrict cardiac output.
2. Local infection at the site of proposed lumbar puncture.
3. Septicemia.

WARNINGS

LOCAL ANESTHETICS SHOULD ONLY BE EMPLOYED BY CLINICIANS WHO ARE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ACUTE EMERGENCIES WHICH MIGHT ARISE FROM THE BLOCK TO BE EMPLOYED, AND THEN ONLY AFTER INSURING THE IMMEDIATE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY RESUSCITATIVE EQUIPMENT, AND THE PERSONNEL RESOURCES NEEDED FOR PROPER MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES.

DELAY IN PROPER MANAGEMENT OF DOSE-RELATED TOXICITY, UNDERVENTILATION FROM ANY CAUSE AND/OR ALTERED SENSITIVITY MAY LEAD TO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST, AND, POSSIBLY, DEATH.

Please refer to full Prescribing Information found at www.spectramedical.com.

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