



**The Leading Global
Manufacturer of State-of-the-Art
Needles and Kit Components**

EST. 1995

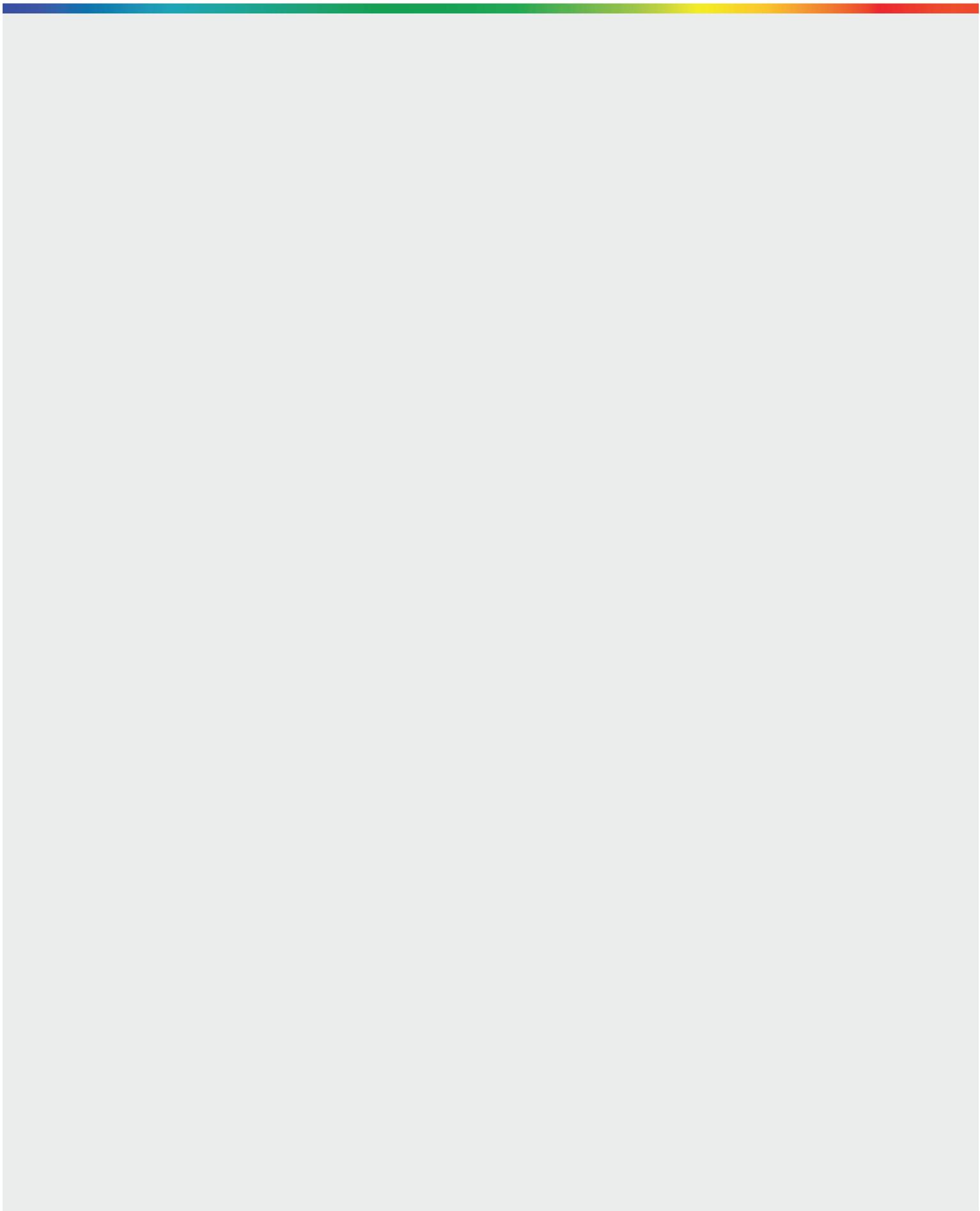


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WELCOME LETTER

Spectra Medical Devices, Inc. was founded in 1995 by Anthony C. Arrigo (known as Tony Spectra). Tony was previously the CEO, President and owner of American Medical Instruments, Inc., a market leader in manufacturing custom procedural needles, which is now the needle division of Tegra Medical.



Current Needle Production Facility



New Fourth Production Facility Under Construction



Spectra Molding Facility

In 2020, Spectra Medical Devices, Inc. celebrated its 25th anniversary as one of the largest procedural needle manufacturers in the world, with substantial market share in over 40 countries. Spectra utilizes the latest state-of-the-art manufacturing, measuring and inspection systems, along with over 225 years of senior staff needle-manufacturing experience. Spectra has been awarded several U.S. patents for special needle processing and products, as well as being an FDA-approved source for Lidocaine ampules and vials, Sodium Chloride ampules and Bupivacaine ampules. In the future, we will be offering several more similar drugs as well.

Our primary focus is on patient safety and achieving substantial growth through quality and innovation. Spectra has five manufacturing plants worldwide, employing over 300 personnel. Our corporate headquarters is located in Wilmington, Massachusetts.

Anthony (Tony) Arrigo, President



Tony being interviewed by NBC TV

THE SPECTRA STORY

Advanced Medical Equipment Requires Advanced Manufacturing

Our mission is to provide physicians with the best performing, most reliable medical equipment possible. At every stage, from design to customer service, we go beyond the standard to achieve that objective.

The most critical step in the process is manufacturing. Our manufacturing equipment, facilities and processes are all state-of-the-art. They are capable of engineering consistently high-quality products that physicians count on for any procedure. At our facilities, we continue to increase automation to our manufacturing production capabilities.

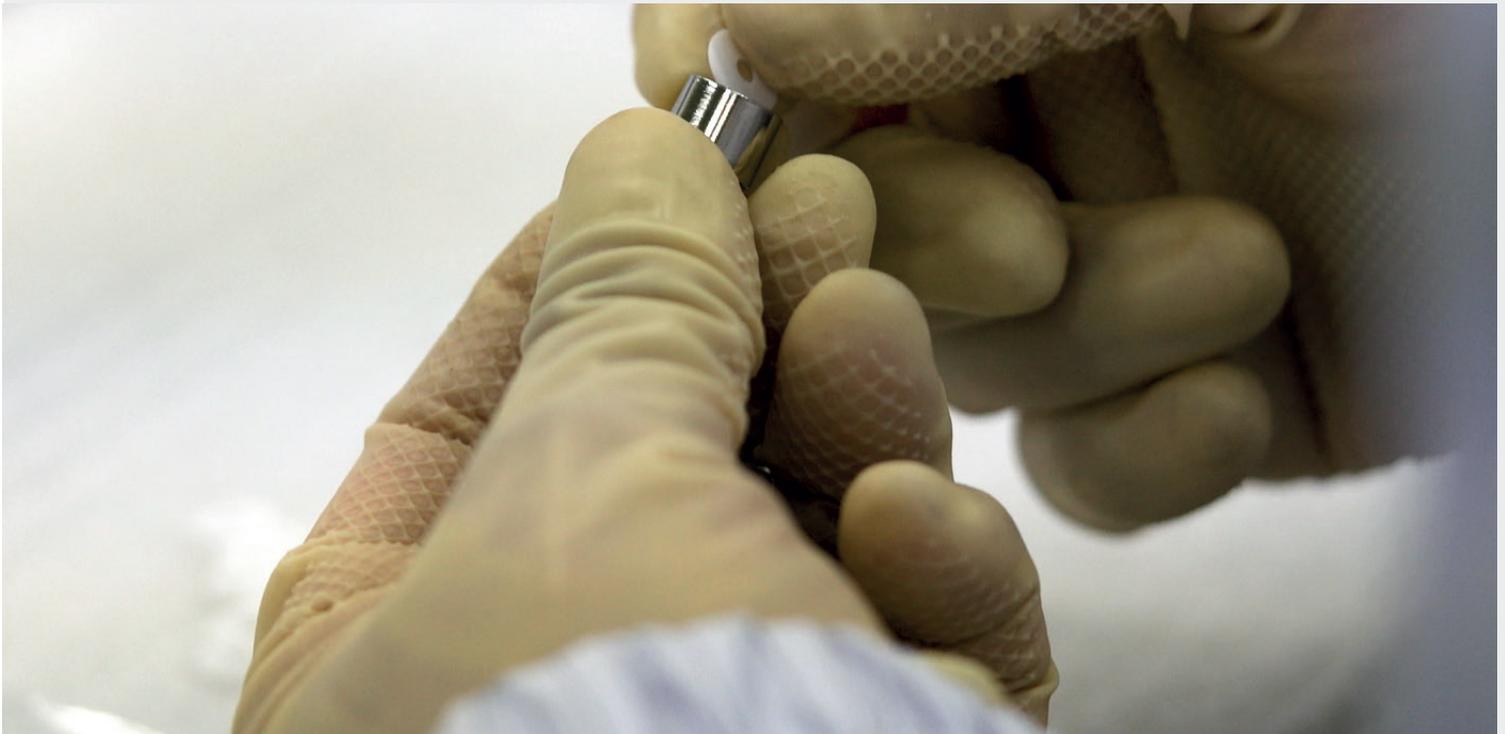
Of course, all physicians are part of an organization with time and budget demands, inventory concerns and other business issues. Spectra is committed to addressing both medical and business concerns that each individual customer faces. Our outstanding customer service department is responsive to all our customers' needs, from meeting deadlines to customizing our product line.

ISO 13485:2016 Registered Certificate #SCC-0076-5



MANUFACTURING

How We Engineer Higher Quality Medical Equipment



Needle manufacturing is an esoteric science. Spectra has been manufacturing needles that are smaller than a human hair for over 25 years. As you can imagine, during the genesis of our company, we had to overcome many adaptive and technical challenges. Overcoming these challenges has prepared our staff to manufacture the widest array of needles in the world.

Creating precision consistently demands sophisticated engineering, precise manufacturing and uncompromising quality control. After extensive global consideration and analysis, Spectra has located its primary production facilities in South Korea, where they offer state-of-the-art technology and an exceptional commitment to quality control.

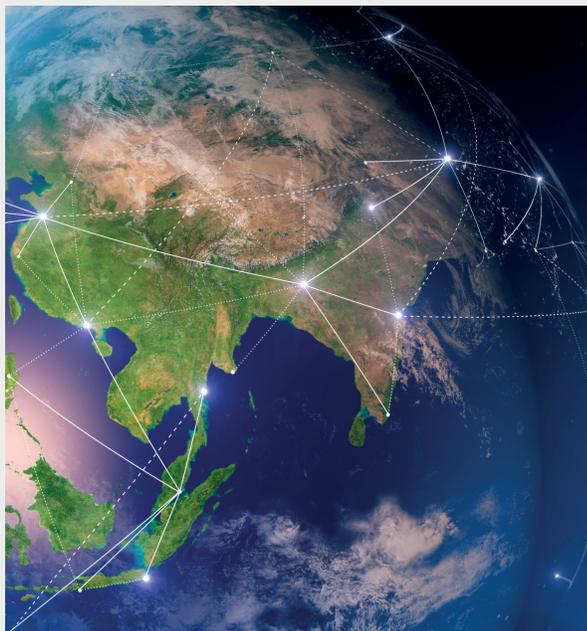
Our production facilities adhere to tight tolerances, exceeding industry standards to continually produce the best medical equipment possible.

INNOVATION AND SERVICES

Constantly Advancing Design to Improve Care

Spectra's extensive engineering and manufacturing capabilities allow us to partner with physicians around the world on a regular basis to design, test and produce innovative and custom needle designs to the highest quality specifications.

In this catalog, you'll learn about some of our proprietary needle innovations, including Cath Glide®, Cath Slide®, Epi-Match®, Guide Glide®, Reduced Advancement Force Radiofrequency (RF) Needles and Spectra Guide® – the global standard for needle echogenicity under ultrasound.



Spectra's Commitment to Customer Satisfaction and Patient Safety

Spectra Medical designs and manufactures the highest quality medical instruments and products to assist physicians in achieving better clinical results while ensuring patient safety and comfort. Our collaborative approach and robust supply chain management system assure that our products arrive where and when they are required, at competitive prices that help our customers meet both their business and patient care objectives.

ULTRASOUND GUIDED NEEDLES

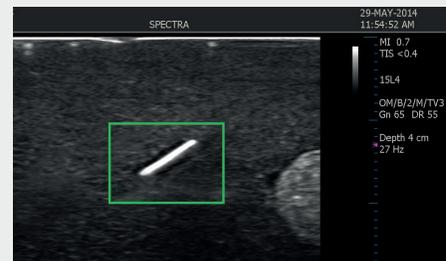
Spectra Guide®

The Standard for Echogenic Clarity Available on Most Needle Styles

As a world leader in echogenic needle design and quality, Spectra has clearly advanced the field of ultrasound-guided procedures with a proprietary dimple design that delivers sharper imaging all the way to the tip of the needle.

What Makes Spectra Guide® Better?

- More and smaller dimple reflectors for a clearer, defined image
- Reduced presence of acoustic shadowing and haloing
- Dimpled right up to the apex so physicians can precisely see the tip of the needle
- Uniform dimples around the needle provide clarity from any angle
- Spectra's production process allows echogenicity on a wide variety of needle styles



Guide Glide II® echogenic technology

Our echogenic configuration optimizes needle visualization under ultrasound guidance. This proprietary technology improves the accuracy of needle placement and is atraumatic to the patient.



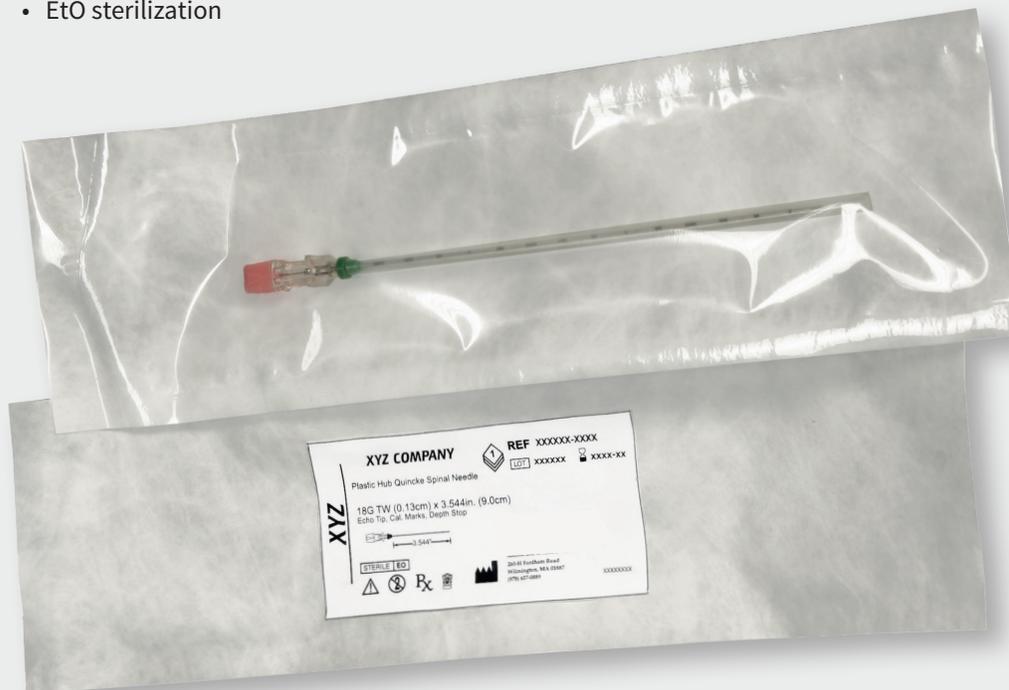
STERILE NEEDLES

Individually Packaged Sterile Needles

Spectra offers both sterile and non-sterile needles. We have in-house packaging and labeling operations.

Features and Options Available:

- Tyvek® chevron peel pouches in chipboard or fluted shelf box
- Studies demonstrate SAL, Bioburden, Non-Pyrogenicity, Non-Toxicity, package integrity and EtO residuals, as well as bacteriostasis and fungistasis
- Standard or customized needles to fit customer specifications
- Customer contracted packaging solutions, specific testing and validation needs available
- Fast, easy customization of private labels
- EtO sterilization



PAIN MANAGEMENT

Epidural Needles

More Options for Physicians

Spectra's epidural needles come with an extensive array of features for various applications and uses.

Features and Options Available:

- 510(k) clearance
- CE 0413 marking
- ISO 80369-6 (NRFit®) compliant hubs
- Epi-Match® technology
- Cath Slide® process ensures unscathed catheter advancement and retraction
- Uses the highest tensile strength 304 stainless steel
- With or without cm depth markings
- Bevel orientation indicator ensures proper alignment
- Metal or plastic hub and stylet
- Fixed wing, removable wing or no wing
- Transparent hub for full visualization of fluids
- Color-coded stylet cap
- Customizable Sharpness: Regular/Dull/Super Dull
- Single use, disposable

Sizes:

- 14GA - 25GA
- 2" - 6" lengths
(custom sizes available upon request)

Applications:

- Epidural catheter placement
- Regional anesthesia pain management
- Pain management

Styles:

- Tuohy, Hustead, Crawford or Weiss



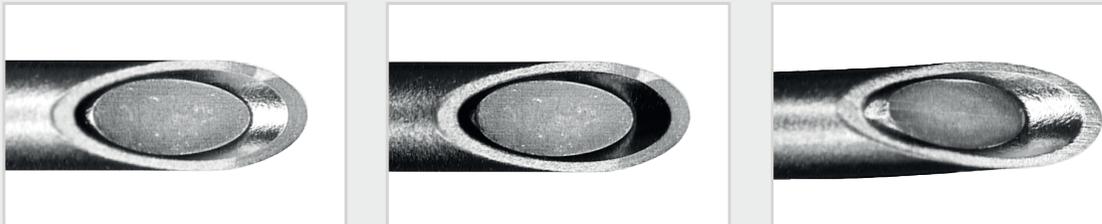
PAIN MANAGEMENT

Epi-Match®

It's vital that an epidural needle advances and passes through a catheter without disruptions. Any catch or resistance can lead to a potentially dangerous situation.

This is why Spectra offers our premium Epi-Match® option and performs Cath Slide® on all epidural needles. The cannula and stylet are ground together to match perfectly.

This eliminates the common protrusion scissoring at the tip or recessions at the heel – two of the causes of resistance and placement errors when introducing the catheter.



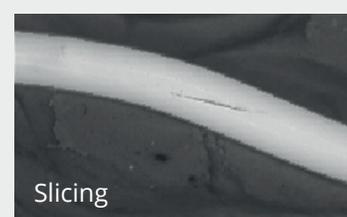
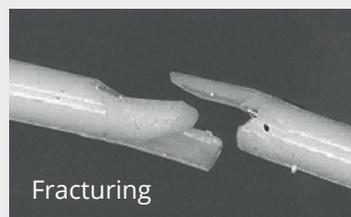
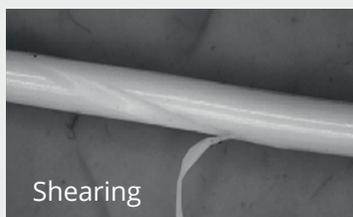
Protrusions and recessions can negatively affect the performance of needles.



Spectra Epi-Match® design eliminates protrusions and recessions.

Cath Slide®

Spectra's Cath Slide® technology is a proprietary blasting process that rounds all internal sharp edges in order to eliminate the chances of damaging the catheter during introduction into the patient's epidural space.



These potentially dangerous failures can be caused by sharp edges on the heel of the standard production epidural needle.

PAIN MANAGEMENT

SCS Lead Introducers

Spinal Cord Stimulator Leads and Electrode Introducers

Internal and external edges are completely rounded by our proprietary process in order to facilitate advancing of spinal cord stimulator lead without skiving, breaking or hang-ups.

Features and Options Available:

- ISO 80369-6 (NRFit®) compliant hubs
- Cath Slide® process ensures unscathed catheter advancement and retraction
- Uses the highest tensile 304 stainless steel
- Eliminates SCS lead cutting, skiving and hang-ups
- Plastic or metal hub
- Metal or plastic stylet
- With or without calibration markings
- Fixed wing, removable wing or no wing
- Color-coded stylet cap
- Curved or straight
- Customizable sharpness
- Bevel orientation indicator ensures proper alignment
- Single use, disposable

Sizes:

- 13GA - 16GA
- 4" - 6.5" lengths
(custom sizes available upon request)

Applications:

- Intrathecal drug delivery
- Neurostimulation



PAIN MANAGEMENT

Spinal Introducer Needles

More Control During Spinal Anesthesia

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

Features and Options Available:

- Uses highest tensile 304 stainless steel
- Aluminum, metal or plastic hub
- Knurled Hub
- Smooth transition for needle insertion and passage
- Single use, disposable

Sizes:

- 19GA - 22GA
- 1" - 3.5" lengths
(custom sizes available upon request)

Applications:

- Cerebrospinal fluid collection (CSF)
- Spinal anesthesia



PAIN MANAGEMENT

Spinal Needles

A Full Selection of Needle Styles and Sizes for Spinal Anesthesia



Spectra's spinal needles use the highest tensile strength 304 stainless steel and are available in custom sizes and configurations to match any procedure and preference.

Features and Options Available:

- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant hubs
- With or without Spectra Guide®
- Uses the highest tensile strength 304 stainless steel
- Clear, plastic hub with color-coded stylet cap
- With or without introducer needles
- With or without cm depth markings
- Depth stop available
- Block Glide® lubrication
- Bevel orientation indicators available
- Single use, disposable

Sizes:

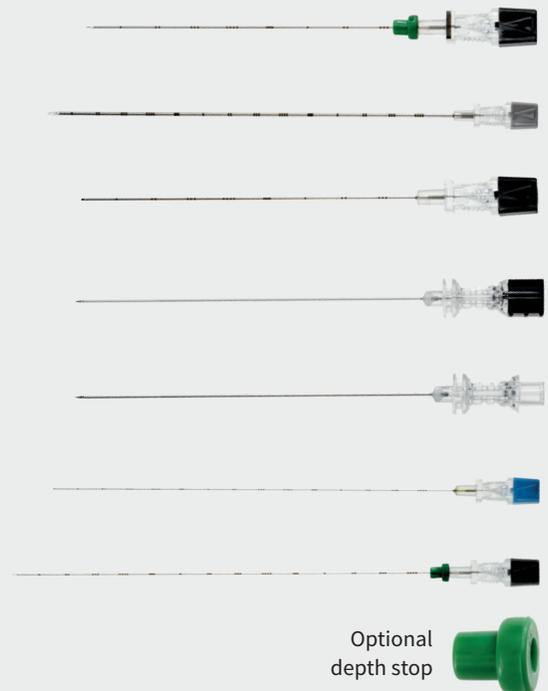
- 18GA - 27GA
- 1.5" - 12" lengths
(custom sizes available upon request)

Application:

- Spinal anesthesia

Styles:

- Quincke, Chiba, Sprotte (Pencil Point) or Whitacre (Pencil Point)



PAIN MANAGEMENT

Echoshot™

Spectra Echoshot™ Injection Needles

Echoshot™ is a disposable lubricated echogenic needle with fluid injection designed for joint injections, peripheral nerve blocks and injection of radio contrast medium.

Features and Options Available:

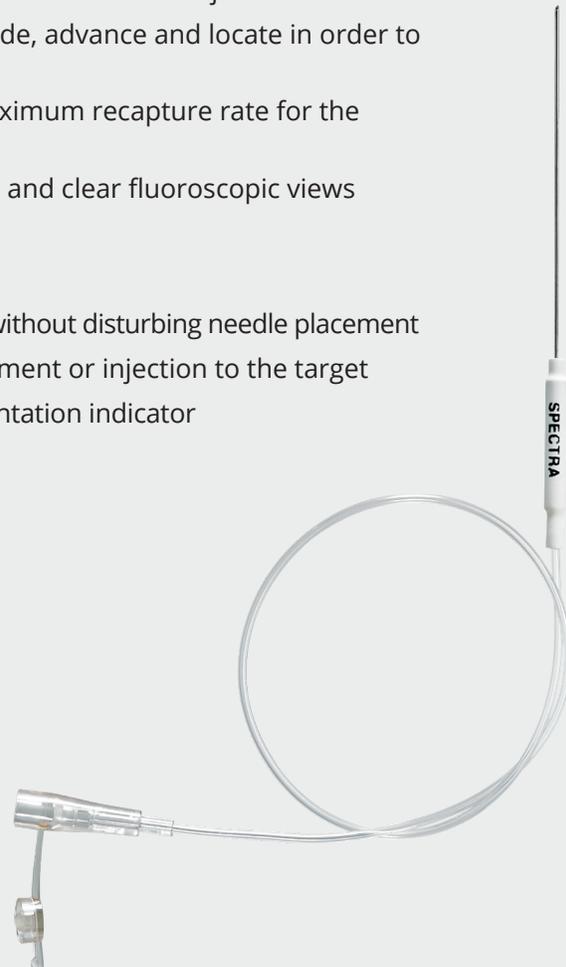
- Disposable, lubricated, echogenic needles with fluid injection line for joint injections, peripheral nerve blocks and injection of radiocontrast medium
- Smooth, steerable shafts with a small ergonomic hub that indicates injection direction
- Echogenic needles allow you to see and precisely guide, advance and locate in order to perform procedures more safely and efficiently
- Spectra Guide® dimpled echogenic field provides maximum recapture rate for the clearest image under ultrasound guidance
- Small ergonomic hub provides comfortable handling and clear fluoroscopic views
- Uses highest tensile strength 304 stainless steel
- 30° bevel with a back-cut secondary bevel
- A 30 cm integral tube and Luer connector for injection without disturbing needle placement
- Designed for easy, controlled steerable needle placement or injection to the target
- "Spectra" marking on the hub serves as the bevel orientation indicator ensuring proper alignment
- Lubricated or non-lubricated needles
- Single use, disposable

Sizes:

- 21GA - 23GA
- 6 -15 cm
(custom sizes available upon request)

Applications:

- Joint injection
- Peripheral nerve blocks
- Injection of radiocontrast medium



PAIN MANAGEMENT

Peripheral Nerve Block (PNB) - Continuous

Spectra Sonic Block™ Echogenic Needles for Precise Control

Spectra's PNB needles provide a maximum visualization, under ultrasound guidance, allowing physicians to clearly see where the tip of the needle is and allowing them to safely and confidently introduce the catheter.

Features and Options Available:

- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant hubs
- Spectra Guide® technology for clarity, precision and safety under ultrasound-guided procedures
- Uses the highest tensile strength 304 stainless steel
- Inner diameter unaffected by echogenic process so catheter advances smoothly
- Bevel orientation indicator ensures proper alignment
- Cath Slide® applied on Tuohy style
- Fixed wing, removable wing or no wing
- Single use, disposable

Sizes:

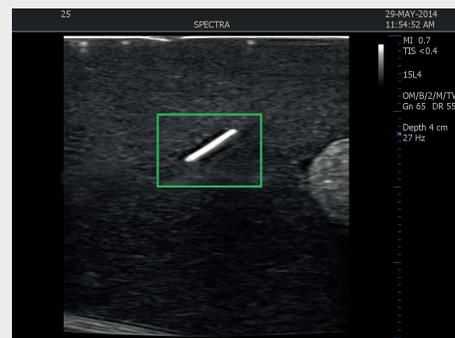
- 16GA - 25GA
- 1" - 7" lengths
(custom sizes available upon request)

Applications:

- Ultrasound-guided injections
- Catheter placement

Styles:

- Tuohy, Quincke, Chiba or Crawford



Spectra's Needle Under Ultrasound Guidance



PAIN MANAGEMENT

Peripheral Nerve Block (PNB) - Single Shot

For Precise Guided and Unguided Electric Nerve Stimulation

Our insulated, single-shot PNB needle is compatible with most generators for needle guidance using stimulation and/or ultrasound.

Features and Options Available:

- 510(k) clearance
- Spectra Guide® technology for clarity, precision and safety under guided ultrasound procedures
- PNB needle with stimulating tip and electrical lead connections to a 2 mm pin connector
- Echogenic or non-echogenic
- B bevel
- Uses the highest tensile strength 304 stainless steel
- Single use, disposable

Sizes:

- 21GA - 23GA
- 2.5" - 6" lengths
(custom sizes available upon request)

Application:

- Nerve stimulation



PAIN MANAGEMENT

Radiofrequency (RF) Needles

Reduced Advancement Force Radiofrequency (RAF)

Spectra Medical Devices Inc. is the leading manufacturer of RF needles in the world, as a result of producing superior quality products and applying state-of-the-art technologies in full compliance with CGMP/QSR regulations. Spectra's RF needles can be used with various probes and generators. Spectra has the widest range of RF needles in the industry with over 100 configurations available.

Features and Options Available:

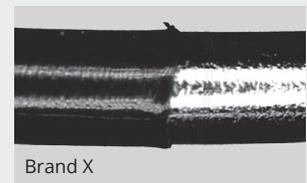
- 510(k) clearance
- CE 0413 marking
- Uses the highest tensile strength 304 stainless steel
- Customizable gauges, needle lengths and active tip lengths
- With or without hub
- Straight, curved, blunt or sharp tip
- Echogenic or non-echogenic
- Lubricated or non-lubricated
- Quincke bevel or lancet bevel
- Single use, disposable

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)

Application:

- Radiofrequency lesioning



Brand X



Brand Y



Spectra (RAF®)

The Advantages of Reduced Advancement Force Radiofrequency (RAF) Technology



Loss of Resistance (LOR) Syringes

Spectra Glass LOR Syringes

Spectra's Glass LOR Syringes are match formed, ensuring seamless plunger action when locating the epidural space.

Features and Options Available:

- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant luer fittings
- Smooth, low friction, consistent plunger movement
- 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

Application:

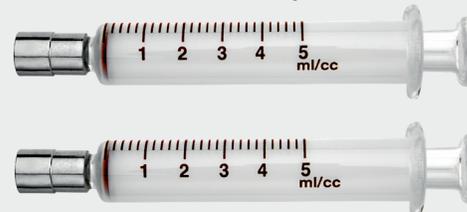
- Used in conjunction with an epidural needle to assist in locating the epidural space



Norprene® Shroud



NRFit®



PHARMACEUTICALS

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

Spectra now offers Bupivacaine Hydrochloride in Dextrose Injection, USP, 0.75% indicated for the production of subarachnoid block (spinal anesthesia).

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

How To Order:

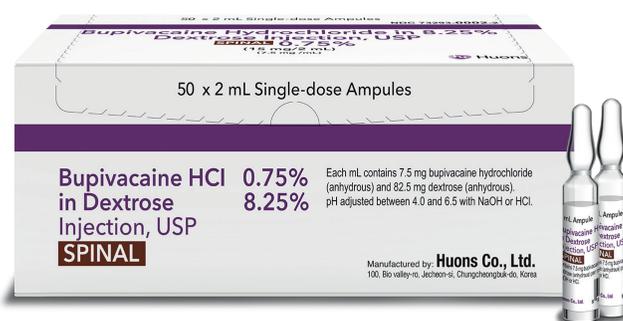
2 mL Single-Dose Glass Ampules*

Box of 50

NDC: 73293-0002-1, 73293-0002-1

**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 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

PHARMACEUTICALS

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

Spectra offers Lidocaine Hydrochloride Injection, USP, 1%, 5 mL 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.

- Lidocaine Hydrochloride Injection, USP, 1%
- Glass Ampules
- Preservative Free
- Manufactured for Spectra Medical Devices, Inc.,
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: 65282-1605-1

**USP Type I 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

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

PHARMACEUTICALS

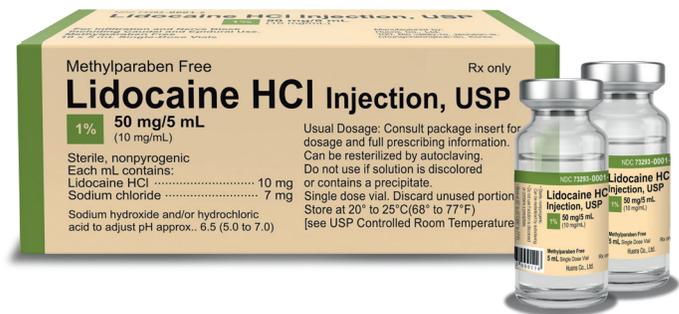
Lidocaine Hydrochloride Injection, USP, 1%, 5 mL Single-Dose Vials

Spectra offers Lidocaine Hydrochloride Injection, USP, 1%, 5 mL 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.

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

How To Order:

5 mL Single-Dose Glass Vials
Box of 10 / Carton of 600
NDC: 73293-001-1, 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

PHARMACEUTICALS

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

Sodium Chloride Injection, USP, 0.9% is used to flush intravascular catheters or as a sterile, isotonic single dose vehicle, solvent or diluent for substances to be administered intravenously, intramuscularly or subcutaneously.

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

How To Order:

5 mL Single-Dose Glass Ampules*
Box of 25 / Carton of 600
NDC: 65282-1505-1

10 mL Single-Dose Glass Ampules*
Box of 25 / Carton of 900
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

Huber Needles and Cannulas

Our Non-Coring Needles and Cannulas Set the Benchmark for Quality

For port access therapies and implantable drug delivery systems, Spectra Huber Needles and Cannulas set the standard for ease and comfort. Spectra is a trusted global source with over 300 million Huber Needles sold worldwide.

Features and Options Available:

- 510(k) clearance
- Uses the highest tensile strength 304 stainless steel
- Plastic hub, metal hub or cannula only
- Plastic hub can be color-coded
- Straight or bent
- Standard or custom configurations
- Single use, disposable
- Straight, 45° or 90° bent and custom configurations

Sizes:

- 19GA – 25GA
- 0.75" – 3.5" lengths

Applications:

- Port access
- Implantable drug delivery systems



Fine Needle Aspiration (FNA) Biopsy Needles

For Precise Sampling of
Tissue for Analysis



Spectra offers a selection of needle sizes and configurations to provide the desired biopsy sample of tissue, cells or fluid, quickly and easily, with or without echogenic guidance.

Features and Options Available:

- 510(k) clearance
- ISO 80369-6 (NRFit®) compliant hubs
- Uses the highest tensile strength 304 stainless steel
- Dimpled echogenic, echogenic blasted or non-echogenic tip
- Plastic or metal hub
- With or without calibration markings
- Bevel orientation indicator ensures proper alignment
- Color-coded stylet hub for instant gauge identification
- Depth stop available
- Single use, disposable

Sizes:

- 18GA – 27GA
- 7 cm – 20 cm lengths

Application:

- Thyroid and other FNA biopsy procedures

Styles:

- Chiba, Franseen, Greene or Whitacre

Tunnelers and Trocars

A Wide Selection for a Range of Applications

Spectra manufactures a complete line of standard and custom tunnelers and trocars, to meet the needs of physicians for a wide range of applications.

Features and Options Available:

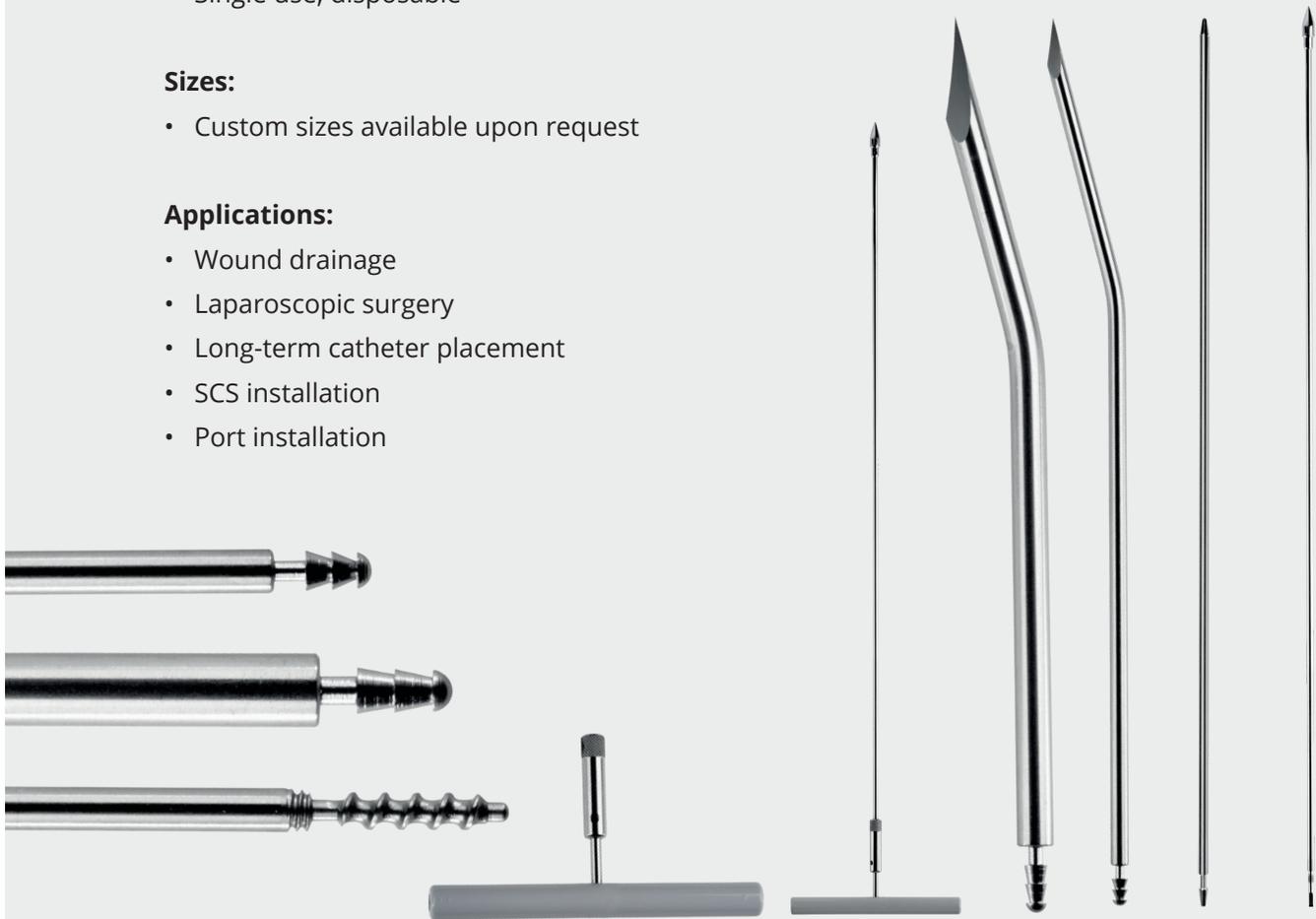
- Class I Medical Devices / Components
- Manufactured to Spectra's high standards
- Single use, disposable

Sizes:

- Custom sizes available upon request

Applications:

- Wound drainage
- Laparoscopic surgery
- Long-term catheter placement
- SCS installation
- Port installation



Prostate Implant Needles

Echogenic Prostate Seed Implant Needles for Placement Accuracy and Control

For oncologists and urologists treating prostate cancer, the precise placement and smooth delivery of the radioactive seeds requires maximum echogenic visibility for accuracy and control.

Features and Options Available:

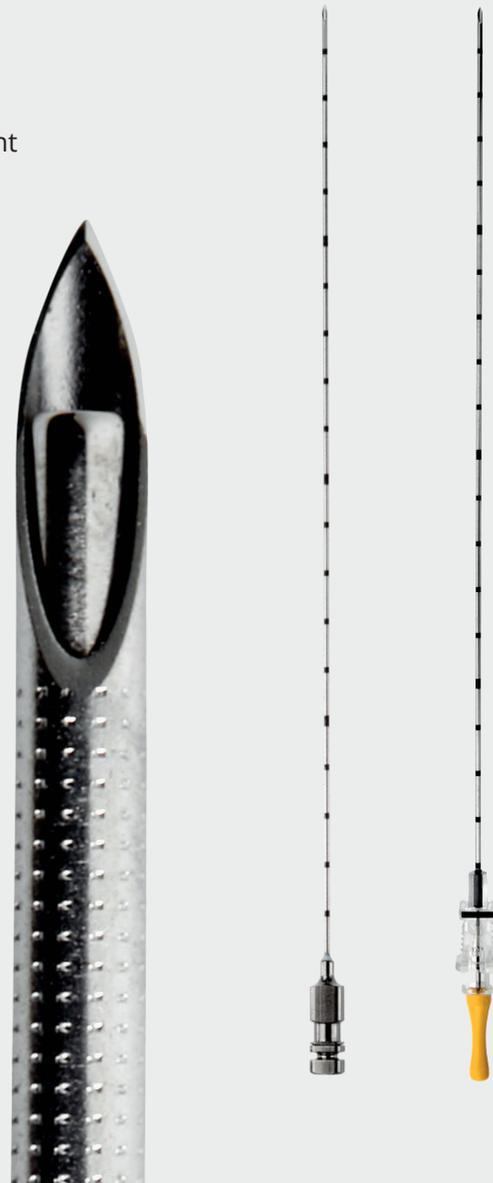
- Uses the highest tensile strength 304 stainless steel
- Bevel orientation indicator ensures proper alignment
- Plastic or metal hub
- Single use, disposable

Sizes:

- 18GA
- 8" length
(custom sizes available upon request)

Application:

- Introducing prostate seed implants



PICC

Guidewire Introducer Needles (GWI)

Specialized Design for Accurate PICC Line Placement

Spectra's combination of precision feature options and unmatched echogenic quality set a higher standard for guidewire introducers.

Features and Options Available:

- 510(k) clearance
- CE 0413 marking
- Uses the highest tensile strength 304 stainless steel
- Guide Glide II® technology optimizes needle visualization under ultrasound guidance
- Bevel orientation indicator ensures proper alignment
- Lubricated or non-lubricated
- Dimpled echogenic, blasted echogenic or non-echogenic
- Wide array of plastic hub styles and colors
- A or B bevel
- Blunt needles available
- Single use, disposable

Sizes:

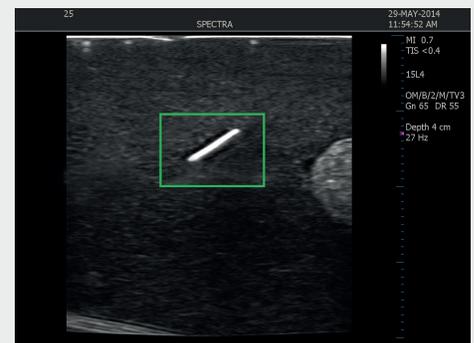
- 18GA - 21GA
- 1.25" - 3.5" lengths
(custom sizes available upon request)

Applications:

- Angiography
- Angioplasty
- PICC

Styles:

- Seldinger, Potts-Cournand or Modified Potts



Spectra's Needle Under Ultrasound Guidance



Scalpels

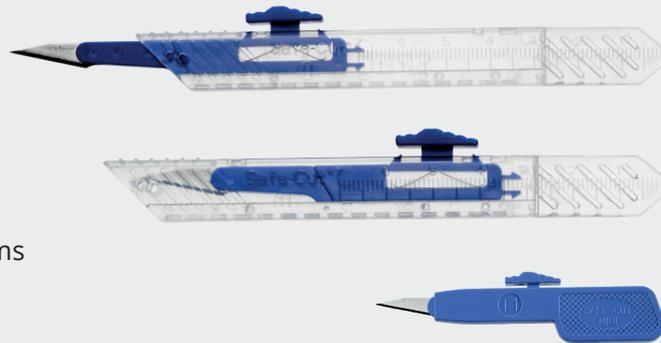
Safe Cut® and Safe Cut® Mini Safety Scalpels that Meet FDA Injury and Prevention Guidance

Spectra's Safe Cut® and Safe Cut® Mini Safety Scalpels have the consistent sharpness, control and strength surgeons demand and are easy to use and uniquely packaged for safety.

Features and Options Available:

- 510(k) clearance
- CE 0413 marking
- Class I Medical Devices
- Top activation button enables left and right-handed use
- Audible button click and tactile sensation confirms lock is in place
- Tactile ruler on side
- Includes precise holes to ensure straight cutting of PICC catheters
- Both scalpels and standalone blades are available

Safety Scalpels



Safe Cut® Safety Scalpel Sizes:

- #10/#11/#15

Safe Cut® Mini Safety Scalpel Sizes:

- #10/#11/#12/#15/#20/#21/#22/#23
#24/#25/#10A/#12B/#15C

Non-Safety Scalpels



Applications:

- Surgical cutting instrument
- Catheter cutter

SURGICAL EQUIPMENT

Single Use Disposable Instruments

Specialized Surgical and Dental Instruments for Procedural Kits

Our instrument catalog has over 150 illustrated pages of specialized surgical and dental instruments completing the full spectrum of custom trays. Contact us for our full catalog of disposable instruments.

Features and Options Available:

- Industry standard floor grade instruments
- Premium grade instruments
- 100% inspected parts in the USA
- A full spectrum of items for custom trays



SURGICAL EQUIPMENT

Red Snapper® Ampule Openers

Red Snapper® Ampule Opener Prevents Sharp-Related Injury

Spectra's Red Snapper® ampule openers are easy to use and ensure that glass ampules are quickly and safely opened, significantly reducing the chances of sharp injuries.

Features and Options Available:

- Biohazard color-coded
- Provides easy disposal of ampule neck
- Reduces the risk of injuries



Applications:

- 1 - 4 mL ampule
- 5 - 10 mL ampule
- 11 - 20 mL ampule

Easy as 1, 2, Snap



Sponges and Strap Clips

We offer straight and curved handled sponges, with 50 and 70 PPI surfaces. We also offer one - and two - hole strap clips.

Features and Options Available:

- Coarse sponge sticks (50 pores/sq. in.)
- Fine sponge sticks (70 pores/sq. in.)
- Straight or angled designs
- Oral swab available



Strap clips



Tubes and Fabrication

Stainless Steel Stock for Fabrication

Spectra offers a comprehensive selection of 304, 304L, 316 and 316L stainless steel tubing and wire, available in lengths, gauges and wall types to enable custom fabrication of medical devices.

Features and Options Available:

- RADIUSING is available upon request

Sizes:

- 0.2' - 10' lengths
(custom sizes available upon request)



WIRE AND TUBING

Wiring and Tubing Chart

Gauge	Wall Type	OD Range	ID Range	Wall
6	RW	.2020 - .2040	.1700 - .1760	0.0150
	TW	.2020 - .2040	.1800 - .1860	0.0100
7	RW	.1790 - .1810	.1470 - .1530	0.0150
	TW	.1790 - .1810	.1570 - .1630	0.0100
8	RW	.1640 - .1660	.1320 - .1380	0.0155
	TW	.1640 - .1660	.1420 - .1480	0.0100
9	RW	.1470 - .1490	.1150 - .1210	0.0150
	TW	.1470 - .1490	.1250 - .1310	0.0100
10	RW	.1330 - .1350	.1040 - .1080	0.0140
	TW	.1330 - .1350	.1120 - .1160	0.0100
	ETW	.1330 - .1350	.1160 - .1200	0.0080
11	UTW	.1330 - .1350	.1200 - .1240	0.0060
	MTW	.1330 - .1350	.1240 - .1280	0.0040
	RW	.1190 - .1210	.0920 - .0960	0.0130
12	TW	.1190 - .1210	.0980 - .1020	0.0100
	ETW	.1190 - .1210	.1020 - .1060	0.0080
	UTW	.1190 - .1210	.1060 - .1100	0.0060
13	MTW	.1190 - .1210	.1100 - .1140	0.0040
	RW	.1080 - .1100	.0830 - .0870	0.0120
	TW	.1080 - .1100	.0890 - .0930	0.0090
14	ETW	.1080 - .1100	.0930 - .0970	0.0070
	UTW	.1080 - .1100	.0970 - .1010	0.0050
	MTW	.1080 - .1100	.1010 - .1050	0.0030
15	RW	.0940 - .0960	.0690 - .0730	0.0120
	TW	.0940 - .0960	.0750 - .0790	0.0090
	ETW	.0940 - .0960	.0790 - .0830	0.0070
16	UTW	.0940 - .0960	.0830 - .0870	0.0050
	MTW	.0940 - .0960	.0880 - .0920	0.0030
	RW	.0820 - .0840	.0610 - .0650	0.0100
17	TW	.0820 - .0840	.0660 - .0685	0.0080
	ETW	.0820 - .0840	.0710 - .0730	0.0055
	UTW	.0820 - .0840	.0730 - .0760	0.0045
18	MTW	.0820 - .0840	.0760 - .0790	0.0030

Gauge	Wall Type	OD Range	ID Range	Wall
15	RW	.0715 - .0725	.0525 - .0555	0.0090
	TW	.0715 - .0725	.0595 - .0615	0.0060
16	ETW	.0715 - .0725	.0615 - .0635	0.0050
	UTW	.0715 - .0725	.0635 - .0655	0.0040
	MTW	.0715 - .0725	.0655 - .0675	0.0030
17	RW	.0645 - .0655	.0455 - .0485	0.0080
	TW	.0645 - .0655	.0525 - .0545	0.0060
	ETW	.0645 - .0655	.0545 - .0565	0.0050
18	UTW	.0645 - .0655	.0565 - .0585	0.0040
	MTW	.0645 - .0655	.0585 - .0605	0.0030
	RW	.0575 - .0585	.0405 - .0435	0.0080
19	TW	.0575 - .0585	.0465 - .0485	0.0050
	ETW	.0575 - .0585	.0490 - .0510	0.0040
	UTW	.0575 - .0585	.0510 - .0530	0.0030
20	MTW	.0575 - .0585	.0530 - .0550	0.0020
	RW	.0495 - .0505	.0405 - .0435	0.0085
	TW	.0495 - .0505	.0375 - .0395	0.0060
21	ETW	.0495 - .0505	.0410 - .0430	0.0040
	UTW	.0495 - .0505	.0430 - .0450	0.0030
	MTW	.0495 - .0505	.0450 - .0470	0.0020
22	RW	.0415 - .0425	.0255 - .0285	0.0075
	TW	.0415 - .0425	.0315 - .0335	0.0050
	ETW	.0415 - .0425	.0340 - .0360	0.0035
23	UTW	.0415 - .0425	.0360 - .0380	0.0025
	MTW	.0415 - .0425	.0380 - .0400	0.0015
	RW	.0355 - .0360	.0230 - .0245	0.0060
24	TW	.0355 - .0360	.0255 - .0270	0.0050
	ETW	.0355 - .0360	.0270 - .0285	0.0040
	UTW	.0355 - .0360	.0290 - .0305	0.0030
25	MTW	.0355 - .0360	.0310 - .0325	0.0020
	RW	.0320 - .0325	.0195 - .0210	0.0060
	TW	.0320 - .0325	.0225 - .0240	0.0045
26	ETW	.0320 - .0325	.0245 - .0260	0.0035
	UTW	.0320 - .0325	.0265 - .0280	0.0025
	MTW	.0320 - .0325	.0285 - .0300	0.0015

WIRE AND TUBING

Wiring and Tubing Chart

Gauge	Wall Type	OD Range	ID Range	Wall
22	RW	.0280 - .0285	.0155 - .0170	0.0060
	TW	.0280 - .0285	.0190 - .0205	0.0040
	ETW	.0280 - .0285	.0215 - .0230	0.0030
	UTW	.0280 - .0285	.0235 - .0250	0.0020
	MTW	.0280 - .0285	.0255 - .0270	0.0010
23	RW	.0250 - .0255	.0125 - .0140	0.0060
	TW	.0250 - .0255	.0165 - .0180	0.0040
	ETW	.0250 - .0255	.0185 - .0200	0.0030
	UTW	.0250 - .0255	.0205 - .0220	0.0020
	MTW	.0250 - .0255	.0225 - .0240	0.0010
24	RW	.0220 - .0225	.0115 - .0130	0.0050
	TW	.0220 - .0225	.0135 - .0155	0.0040
	ETW	.0220 - .0225	.0155 - .0170	0.0030
	UTW	.0220 - .0225	.0175 - .0190	0.0020
	MTW	.0220 - .0225	.0195 - .0210	0.0010
25	RW	.0200 - .0205	.0095 - .0110	0.0050
	TW	.0200 - .0205	.0115 - .0130	0.0040
	ETW	.0200 - .0205	.0135 - .0150	0.0030
	UTW	.0200 - .0205	.0155 - .0170	0.0020
	MTW	.0200 - .0205	.0175 - .0185	0.0010
26	RW	.0180 - .0185	.0095 - .0110	0.0040
	TW	.0180 - .0185	.0115 - .0130	0.0030
	ETW	.0180 - .0185	.0130 - .0145	0.0020
	UTW	.0180 - .0185	.0145 - .0155	0.0015
	MTW	.0180 - .0185	.0155 - .0165	0.0010
27	RW	.0160 - .0165	.0075 - .0090	0.0040
	TW	.0160 - .0166	.0095 - .0110	0.0030
	ETW	.0160 - .0165	.0115 - .0130	0.0020
	UTW	.0160 - .0165	.0130 - .0140	0.0015
	MTW	.0160 - .0165	.0140 - .0150	0.0010
28	RW	.0140 - .0145	.0065 - .0080	0.0035
	TW	.0140 - .0145	.0085 - .0100	0.0025
	ETW	.0140 - .0145	.0100 - .0110	0.0020
	UTW	.0140 - .0145	.0110 - .0120	0.0015
	MTW	.0140 - .0145	.0120 - .0130	0.0010

Gauge	Wall Type	OD Range	ID Range	Wall	
29	RW	.0130 - .0135	.0065 - .0080	0.0030	
	TW	.0130 - .0135	.0080 - .0090	0.0025	
	ETW	.0130 - .0135	.0090 - .0100	0.0020	
	UTW	.0130 - .0135	.0100 - .0110	0.0015	
	MTW	.0130 - .0135	.0110 - .0120	0.0010	
30	RW	.0120 - .0125	.0055 - .0070	0.0030	
	TW	.0120 - .0125	.0070 - .0080	0.0025	
	ETW	.0120 - .0125	.0080 - .0090	0.0020	
	UTW	.0120 - .0125	.0090 - .0100	0.0015	
	MTW	.0120 - .0125	.0100 - .0110	0.0010	
31	RW	.0100 - .0105	.0040 - .0055	0.0025	
	TW	.0100 - .0105	.0055 - .0070	0.0020	
	ETW	.0100 - .0105	.0070 - .0080	0.0015	
	UTW	.0100 - .0105	.0080 - .0090	0.0010	
	32	RW	.0090 - .0095	.0035 - .0050	0.0025
TW		.0090 - .0095	.0050 - .0060	0.0020	
ETW		.0090 - .0095	.0060 - .0070	0.0015	
UTW		.0090 - .0095	.0070 - .0080	0.0010	
33		RW	.0080 - .0085	.0035 - .0050	0.0020
	TW	.0080 - .0085	.0050 - .0060	0.0015	
	ETW	.0080 - .0085	.0060 - .0070	0.0010	
	34	RW	.0070 - .0075	.0025 - .0040	0.0020
		TW	.0070 - .0075	.0040 - .0050	0.0015
ETW		.0070 - .0075	.0060 - .0070	0.0015	
35		RW	.0050 - .0055	.0015 - .0030	0.0015
		TW	.0050 - .0055	.0030 - .0040	0.0010
	36	RW	.0040 - .0045	.0050 - .0060	0.0015
		TW	.0040 - .0045	.0060 - .0070	0.0010

GLOSSARY OF TERMS

AQL (ACCEPTABLE QUALITY LEVELS): A statistical method of sampling by which a predetermined percentage of parts can be accepted as a process average.

ANGLE OF ROTATION: The included angle of the Diamond Point.

ANNEAL: To subject metal to high heat with a subsequent cooling to make it more malleable.

ANODIZE: To subject aluminum to an electrolytic action in order to coat it with a protective film.

ANTICORE BLAST: A blasting operation to dull the heel of the bevel in order to reduce coring.

ASSEMBLY: A cannula plus a hub (also may include packaging and/or protective material or internal components such as filters, diaphragms, etc.)

BEVEL: The angled surface formed on the cannula when a needle point is ground. A typical diamond point has three bevels. The main bevel is partially ground away to form two side bevels.

BEVEL LENGTH: The longest distance of the bevel, usually measured from the tip of the needle to the most proximal area of grinding behind the heel. Side Bevel Length is measured between 1) the juncture of side bevel and the outside surface of tubing and 2) the tip of the needle.

BURRS: Deflection of the point, perceptible to feel.

CANNULA: Small pointed hollow stainless steel tube for insertion into the body. (When hub is added it becomes a "NEEDLE").

CHAMFER: The blending of the O.D. into the I.D., which is formed by angle or radius.

CLEAN: Free from dirt or pollution (Not sterile).

CORING: The cutting of a plug of tissue or port septum when the needle passes through.

CRUXE: The point of the inside wall where the primary and secondary angle meet after rotation.

CUTOFF: Tubing cut to length with no round bevel.

DIAMOND POINT: The length of the secondary angle after rotation, which is measured from the tip to the longest outside grind.

DISTAL END: The end of the needle farthest from the hub.

FEATHER: A thin portion of metal on the cannula that could potentially break off during use.

FLARE: To spread or curve outward. Pertaining to a cannula, it is the spreading of the tubing to a larger diameter.

FLASH: Excessive material on plastic, usually occurring at the mold parting lines.

FREE LENGTH (or NEEDLE LENGTH): The distance between the point of the cannula and the point where the hub starts; i.e. only the distance the cannula is exposed not covered by the hub. Sometimes referred to as USABLE LENGTH.

GG-N-00193: Interim Federal Specification covering sterile disposable hypodermic needles with regular bevel point.

GG-N-196: U.S. Government Specification regarding medical cannula and needles.

GAUGE: O.D. of the needle or cannula, expressed as a Stubbs Gauge Number (See tubing specification chart).

GRIT BLAST: An extra heavy blast on the heel for 1) anti-coring, or 2) to roughen the O.D. of the cannula.

HEEL OF BEVEL: The proximal rounded inner-edge of the point lumen.

HOOK: A burr where a deflection of the point is in excess of .002 inches.

HUB: The part attached to the cannula to make a needle, to enable it to be attached to a syringe or other device.

HUBER POINT: A point which is bent to allow the opening to be on the side.

I.D.: Internal diameter of tubing.

INTRA-ARTERIAL: Within an artery.

INTRADERMAL: Within the skin.

INTRAMUSCULAR: Within the substance of a muscle.

INTRAVENOUS: Within a vein.

GLOSSARY OF TERMS

INSERT MOLDING: Method of inserting a cannula during a plastic molding process.

LUER LOCK: A part which locks a needle to a syringe by means of a threaded hub.

LUER TAPER: This taper is standardized by the American Standard Association's Standard 270.1-1955.

LUMEN: The hole through the cannula tube.

MICRON: A unit of length -- a thousandth part of one millimeter.

NEEDLE (or NEEDLE ASSEMBLY): A cannula with a hub attached.

O.D.: Outside diameter of tubing.

OBTURATOR: A solid rod having a handle, used to occlude the lumen of a needle.

OCCLUDE: To block or close off.

OPTICAL COMPARATOR: An electronic device used to inspect and measure the angular configuration of bevel characteristics on the cannula after grinding.

OVERALL LENGTH: The full length of the needle -- from the point of the cannula to the farthest end of the hub; i.e. includes the part of the cannula covered by the hub.

PARTICULATE MATTER: Any foreign substance contaminating a parenteral solution. These particles can be characterized according to their morphological and optical properties and evaluated under high magnification.

PARENTERAL INJECTION: Injection of substances into the body through any route other than via the alimentary canal; such as subcutaneous, intravenous, intramuscular or intrathecal injection.

PERMEABILITY: The property of stainless steel tubing which determines its relative influence in a magnetic field. This characteristic is often specified by customers depending on the end use of the product.

PENETRATION TESTS: Testing procedure used to measure the sharpness or penetration characteristics of a cannula when passed through a standard membrane. Spectra uses a Lloyd penetration tester for this purpose.

PROXIMAL END: The end of the cannula closest to the hub.

PYROGEN: A fever-inducing substance. Cleanliness in all phases of manufacturing and handling is essential to avoid a pyrogenic product.

STERILE: Free from living microorganisms.

STUBS NEEDLE GAUGE: A system denoting O.D. size of a cannula. This is stated in numbers ranging from 7 through 35 -- the larger the number is the smaller the needle is. (See tubing specification chart.)

STYLET: A solid rod with a handle. The tip is ground to fit the bevel of the needle through which it is run. This stylet, when introduced with the needle, helps prevent coring.

SUBCUTANEOUS: Under the skin.

SWAGING: 1) A method for crimping a hub onto a cannula by the use of pressure. 2) A process for shaping by compressing the O.D. of the cannula.

TROCAR: A three sided, sharp, pointed stylet fitted with a cannula to be inserted into a body cavity.

VENIPUNCTURE: The puncture of a vein with a needle.

WALL TYPES: The tubing wall is described by one of the following:

- RW: Regular wall
- TW: Thin wall
- ETW: Extra thin wall
- UTW: Ultra thin wall
- MTW: Micro thin wall

Notice: Every effort has been made to depict and describe the product accurately; however, we reserve the right to alter and make modifications to certain products from time to time and without notice. Measurements may vary slightly.

HUB COLOR CHART

HUB U.S. COLOR CHART

30G	29G	28G	27G
26G	25G	24G	23G
22G	21G	20G	19G
18G	17G	16G	15G
14G	13G	12G	
11G	10G		

HUB EUROPEAN COLOR CHART

30G	29G	28G	27G
26G	25G	24G	23G
22G	21G	20G	19G
18G	17G	16G	15G
14G	13G	12G	
11G	10G		







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