Combined Spinal and Epidural Anesthesia Instructions for Use

PERIFIX™ Continuous Epidural Catheters include the following:

Key Measurements: Catheter Markings	
PERIFIX™ Epidural Catheter and PERIFIX™ FX Epidural Catheter	5.5 cm (1 ring)...10.5 cm (2 rings)... 15.5 cm (3 rings)...20.5 cm (4 rings) in 1 cm increments.
PERIFIX™ ONE Epidural Catheter	5 cm (1 ring)...10 cm (2 rings)... 15 cm (3 rings)...20 cm (4 rings) in 1 cm increments.
PERIFIX™ ONE Pediatric Epidural Catheter	2 cm (1 ring)...10 cm (2 rings)... 15 cm (3 rings)... 20 cm (4 rings) in 1 cm increments.
The solid wide warning mark indicates exit of catheter from needle when using the Thread Assist Guide and a PERIFIX™ Epidural Needle. The catheter will exit 1 cm before the warning mark when not using the Thread Assist Guide.	

NOTES:
- See immediate container label for components contained in kit.
- All components required for the procedure may not be included with kit.
- See drug product(s) and/or drug product(s) Package Insert(s) for full disclosure information and storage conditions.
- Refer to specific device sections for Instructions for Use (including Indications for Use).
- For kits containing Needle Block Foam with Holder: Push needles into foam after use. Do not reuse needles after they have been placed into foam as particulate matter may adhere to the needle. Dispose of in sharps container.
- For kits containing NRFit® components: NRFit components are designed to be compatible with devices intended for neuraxial applications.

Contraindications Associated with Combined Spinal and Epidural Procedures
- Coagulation disorders, anticoagulant therapy
- Infection or hematoma around the desired puncture site
- Sepsis
- Known hypersensitivity to one or more materials employed or to local anesthetics
- Hypovolemia
- Shock
- Acute cerebral or spinal cord disease
- Increased intracranial pressure
- Anatomical anomalies at the injection site
- Not for use with tunneling technique (PERIFIX® FX Epidural Catheter Only)

Risks Associated with Combined Spinal and Epidural Procedures
- Hypotension, which may lead to cardiac arrest and/or respiratory arrest
- Post dural puncture headache
- Toxic effect of local anesthetic
- Neural damage resulting from toxic reactions to local anesthetic (excessively high dose, intraneural injection)
- Arachnoiditis and meningitis
- Cauda equina syndrome
- Hematoma after puncturing a blood vessel
- Inadvertent high epidural block
- Total spinal block following intrathecal injection
- Mechanical neural damage caused by needle tip or intraneural injection
- Inadvertent intravascular injection of local anesthetic

Instructions for Use: Use Aseptic Technique.
- Visually inspect sterile barrier system for breaches and integrity prior to use. Do not use if packaging or product is damaged or contaminated or if protective caps are loose or missing. Use of damaged or contaminated device might lead to injury, illness or death of the patient.

1. Select and prepare insertion site per institutional protocols.
2. For kits containing drugs, shake and inspect ampuls. Prepare drugs for use by standing ampuls upright in circular depressions in the tray.
   CAUTION: IF CRACKED, CLOUDY OR UNDERFILLED, DO NOT USE AMPUL(S).
3. Aspirate appropriate drugs using FILTER STRAW Particulate Matter Filter with syringe.
4. Perform skin wheal.
5. Perform Epidural puncture. Use notch in needle hub to determine what direction the inserted catheter will follow. Remove stylet and perform appropriate test to determine proper placement using preferred loss-of-resistance technique.
   WARNINGS:
   - DO NOT APPLY EXCESSIVE FORCE DURING NEEDLE ADVANCEMENT. DO NOT UTILIZE NEEDLE IF IT BENDS OR TIP BECOMES DAMAGED. NEEDLE WITH DAMAGED TIP INCREASES THE RISK OF INTRATHECAL OR INTRAVASCULAR PLACEMENT.
   - IF RESISTANCE IS FELT DURING ADVANCEMENT OF THE NEEDLE, CAREFULLY CORRECT THE ORIENTATION OF THE NEEDLE BUT NEVER APPLY EXCESSIVE FORCE.
6. IF USING ESPOCAN DOCKING SYSTEM: Refer to ESPOCAN Docking System Instructions for Use.
   WARNING: ESPOCAN SETS WITH DOCKING SYSTEM MUST NOT BE USED WITHOUT DOCKING SYSTEM BECAUSE SPINAL NEEDLE WILL BE TOO LONG (TIP TO TIP PROTRUSION) IN THIS CASE AND INADVERTENT PUNCTURE OF VENTRAL SIDE OF DURAL SAC MAY OCCUR.
7. Insert spinal needle through the epidural needle and perform dural puncture. The spinal needle should be introduced until the needle perforates the dura and CSF flow is identified upon removal of the spinal needle stylet.
   WARNINGS:
   - DO NOT UTILIZE NEEDLE IF IT BENDS OR TIP BECOMES DAMAGED. NEEDLE WITH DAMAGED TIP INCREASES THE RISK OF POST DURAL PUNCTURE HEADACHE DUE TO EXTENDED PERFORATION OF DURA MATER. DO NOT APPLY EXCESSIVE FORCE DURING NEEDLE ADVANCEMENT, NEEDLE MAY BEND OR EVENTUALLY BREAK.
   - IF BLOOD IN THE CSF CONTINUES TO BE SEEN AFTER REMOVAL OF STYLET, WITHDRAW THE NEEDLE AND RETRY AT A DIFFERENT INTERVERTEBRAL SPACE.
   - IF NO CSF IS OBSERVED, ROTATE THE NEEDLE TO ALL FOUR QUADRANTS AND CAREFULLY ASPIRATE UNTIL CSF IS VISIBLE. IF THIS PROCEDURE DOES NOT SHOW ANY FLOW OF CSF, REPEAT THE SPINAL/LUMBAR PUNCTURE.
   - IF PARESTHESIA OCCURS AFTER REACHING THE SUBARACHNOID SPACE, THE NEEDLE SHOULD BE SLIGHTLY WITHDRAWN.
   - IF PARESTHESIA OCCURS DURING INJECTION, THE NEEDLE SHOULD BE REPOSITIONED PRIOR TO CONTINUING THE INJECTION.
8. Inject the anesthetic drug according to the manufacturer's Package Insert(s).

9. Following injection of the spinal anesthetic, remove spinal needle and introduce epidural catheter through the epidural needle using the Thread Assist Guide. Insert catheter to desired depth. The guide will increase longitudinal stability of the catheter. Use notch in needle hub to determine what direction the inserted catheter will follow.
   PRECAUTION: Advancing the catheter more than 5 cm past the needle tip may increase the likelihood of kinking or knotting.
   CAUTION: DO NOT WITHDRAW CATHETER THROUGH THE NEEDLE BECAUSE OF THE POSSIBLE DANGER OF SHEARING OR KINKING.
   9a. IF USING A PERIFIX™ FX CATHETER: Observe the flash-back windows for potential blood. This may indicate penetration of vascular structures or dura, and the procedure should be discontinued or attempted at another interspace.
   9b. IF USING DISPENSER: Extract catheter from the dispenser by feeding the catheter directly into the needle. If resistance is felt, uncoil the dispenser and proceed with threading the catheter. Extract the full length of catheter from the dispenser.
10. Remove needle and Thread Assist Guide over catheter while holding catheter tightly in place.
11. Fully insert catheter into catheter connector. Refer to Catheter Connector Instructions for Use.
    WARNING: DURING CONNECTION TO A CATHETER CONNECTOR, THE CATHETER MAY NOT BE FULLY INSERTED INTO THE CONNECTOR RESULTING IN THE POTENTIAL FOR LEAKAGE OF ANESTHETIC AGENT INTENDED FOR DELIVERY TO THE PATIENT VIA THE CATHETER. DURING MANIPULATION OF THE CONNECTOR WHEN ATTACHING ANESTHESIA DELIVERY DEVICE, THE CONNECTOR MAY BE INADVERTENTLY UNLOCKED, ALLOWING CATHETER TO COME LOOSE FROM THE CONNECTOR RISKING CONTAMINATION OF THE PROXIMAL END OF THE CATHETER, AND/OR INTERRUPTION OF ANESTHETIC DELIVERY.
12. **NOTE: IF USING TEST DOSE:** By the time the epidural catheter has been inserted and attached to a catheter connector the spinal anesthesia may be well developed. An epidural test dose given at this time will not be able to diagnose intrathecal injection. The reduced ability to detect catheter malposition using an epidural test dose should be considered in the selection of this technique and the choice of agents. If an epidural injection becomes necessary before spinal blockade has worn off, small incremental doses should be given at 3 to 5 minute intervals until the effective analgesia is restored. Epidural injections will have a more rapid onset, and more pronounced effect, in the presence of a receding spinal block, and the effect of each increment must be carefully assessed. If the operative procedure has been completed without an epidural injection, the spinal block should be allowed to wear off prior to administration of the test dose.
13. Remove plastic sterility cap and attach anti-bacterial filter or PERIFIX™ 0.2 µm filter (fluid retention is approximately 0.2 mL) or anesthetic administration device.
    CAUTION: DO NOT WET PERIFIX™ 0.2 µm FILTER WITH DISINFECTANTS CONTAINING ALCOHOL AS THIS MAY RESULT IN CRACKS IN THE FILTER HOUSING.
    13a. IF USING PINPAD™ SECUREMENT DEVICE: Filter may be attached to PinPad Securement Device by inserting the post on the PinPad Securement Device into the receptacle in the base of the filter. Peel off adhesive backing to the PinPad Securement Device and affix to the patient.
14. Administer epidural anesthetic as needed according to the manufacturer's Package Insert(s).
15. Secure catheter in place with securement device.
16. Apply dressing to the catheter site.
17. Open and remove catheter connector. Refer to Catheter Connector Instructions for Use.
18. To remove catheter: Grasp catheter close to skin and remove slowly with a steady constant pull force.
    CAUTION: WHEN REMOVING CATHETER, EXCESSIVE FORCE SHOULD NEVER BE APPLIED.
    If resistance is encountered; stop, reposition patient, and attempt removal again.
    WARNING: IF FURTHER RESISTANCE IS ENCOUNTERED DURING CATHETER REMOVAL, WAIT FOR THE BLOCK TO COMPLETELY WEAR OFF BEFORE TRYING AGAIN. THE PATIENT WILL BE UNABLE TO PROVIDE OBJECTIVE FEEDBACK AS TO PAIN AND ANESTHESIA IF THE BLOCK IS STILL EFFECTIVE.
19. Inspect catheter to ensure complete removal.
    CAUTION: FOLLOWING REMOVAL, INSPECT DISTAL TIP FOR CONTINUITY. THE MARK ON THE TIP WILL VERIFY THAT THE ENTIRE CATHETER HAS BEEN RETRIEVED.

PERIFIX™ FX *Springwound* Epidural Catheter

Description: The PERIFIX™ FX *Springwound* Epidural Catheter is comprised of a flexible spring wire core enclosed within a soft copolymer jacket.

Indications for Use: The PERIFIX™ FX *Springwound* Epidural Catheter is intended for administration of local anesthetic agents into the epidural space to provide continuous epidural or caudal anesthesia. The catheter should be removed or replaced every 72 hours.

Contraindication: Known hypersensitivity to one or more materials employed

Materials Used: Stainless Steel, PP, PEBAX, Blue Ink (PRC26, PRC27, PRC28)

MRI Safety Information

MR

MR Conditional
The PERIFIX™ FX *Springwound* Epidural Catheter is MR Conditional.
For all MR Examinations: A patient implanted with the PERIFIX™ FX *Springwound* Epidural Catheter may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition/Information
Device Configuration	Closed-Tip Multi-Port or Open-Tip Uniport Not Filled or Filled with Any Liquid or Any Drug
Static Magnetic Field Strength (B0)	1.5T and 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 Gauss/cm) 1.5T 17 T/m (1700 Gauss/cm) 3.0T*
RF Excitation	Any
RF Transmit Coil Type	Any
Operating Mode	Normal Operating Mode
RF Conditions	Whole-Body Averaged SAR ≤ 2 W/kg

Scan Duration	2 W/kg whole-body averaged SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Regions	Any landmark is acceptable.
Image Artifact	The presence of the PERIFIX™ FX *Springwound* Epidural Catheter may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.
Additional Instructions	Ensure proper and secure fixation of the PERIFIX™ FX *Springwound* Nerve Block Catheter to the patient using an appropriately applied dressing. Failure to ensure the secure fixation of the PERIFIX™ FX *Springwound* Nerve Block Catheter to the patient's skin can result in a displacement of the catheter. * For patient landmarks that will place the catheter inserted region inside the MRI bore, and for patients positioned prone or on their side, the edge of the body at the catheter location must be at least 10 cm inside from the wall of the magnet bore.

MRI WARNINGS:

- NO LOCAL RF TRANSMIT COIL SHOULD BE PLACED OVER THE PERIFIX™ FX *SPRINGWOUND* EPIDURAL CATHETER. PLACING A LOCAL RF TRANSMIT COIL OVER THE PERIFIX™ FX *SPRINGWOUND* EPIDURAL CATHETER CAN RESULT IN SERIOUS AND PERMANENT INJURY INCLUDING COMA, PARALYSIS, OR DEATH.
- DISCONTINUE THE MRI IMMEDIATELY IF THE PATIENT BECOMES UNRESPONSIVE TO QUESTIONS OR EXPERIENCES ANY HEATING, PAIN, SHOCKING SENSATIONS, UNCOMFORTABLE STIMULATION, OR UNUSUAL SENSATIONS.
- MR SCANS MUST BE CONDUCTED USING THE STATED MRI EQUIPMENT AND SCAN CONDITIONS. FAILURE TO FOLLOW ALL WARNINGS AND GUIDELINES RELATED TO MRI CAN RESULT IN SERIOUS AND PERMANENT INJURY, INCLUDING COMA, PARALYSIS, OR DEATH.
- ENSURE PROPER AND SECURE FIXATION OF THE PERIFIX™ FX *SPRINGWOUND* EPIDURAL CATHETER TO THE PATIENT'S BACK. FAILURE TO ENSURE THE SECURE FIXATION OF THE PERIFIX™ FX *SPRINGWOUND* EPIDURAL CATHETER TO THE PATIENT'S SKIN CAN RESULT IN A DISLOCATION OF THE CATHETER.
- AFTER MRI CHECK FOR CATHETER DISLOCATION. CHECK THE CORRECT PLACEMENT OF THE PERIFIX™ FX *SPRINGWOUND* EPIDURAL CATHETER AFTER THE MRI. FAILURE TO ENSURE CORRECT PLACEMENT OF THE CATHETER AFTER THE MRI CAN RESULT IN INCORRECT OPERATION OF THE PERIFIX™ FX *SPRINGWOUND* EPIDURAL CATHETER AND INCORRECT PATIENT TREATMENT.

WARNINGS:

- NOT INTENDED FOR INTRAVENOUS OR SPINAL INJECTION.
- INADVERTENT INTRAVENOUS INJECTION MAY BE FOLLOWED BY SYSTEMIC TOXIC EFFECTS FROM THE LOCAL ANESTHETIC AGENT WITH CONVULSIONS AND POSSIBLE CARDIOVASCULAR COLLAPSE.
- INADVERTENT INJECTION INTO THE SUBARACHNOID OR SUBDURAL SPACE MAY BE FOLLOWED BY RAPID AND TOTAL SPINAL ANESTHESIA, VASCULAR HYPOTENSION, UNCONSCIOUSNESS, AND/OR APNEA.
- INADVERTENT DURAL PUNCTURE MAY RESULT IN HEADACHE AND OTHER NEUROLOGICAL SYMPTOMS.
- INJECTION OF EXCESSIVE DOSES OR CONCENTRATION OF LOCAL ANESTHETIC AGENTS CAN CAUSE NERVE DAMAGE.
- DO NOT CUT THE PERIFIX™ FX *SPRINGWOUND* EPIDURAL CATHETER.

ULTRASOUND NOTES *(If used with the aid of Ultrasound):*

- Consult Ultrasound Imaging Machine manufacturer Instructions for Use.
- Visibility of catheter may depend on a number of factors such as proper setting of ultrasound unit, patient related conditions of tissue, artifacts, proper alignment of ultrasound probe, catheter insertion angle, and catheter depth.

PERIFIX™ ONE Epidural Catheter

Indications for Use: The PERIFIX™ ONE Catheter is intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery. Routes of Administration include epidural and perineural (peripheral nerve block) with a duration of use no longer than 72 hour.s.

Contraindication: Known hypersensitivity to one or more materials employed

Materials Used: PA, PUR, Yellow 138

NOTES:

- For the 20 Ga. catheter, the catheter has been tested for flow rates up to 35 mL/hr.
- For the 24 Ga. catheter, the catheter has been tested for flow rates up to 10 mL/hr.

Flow rates outside this range may not meet performance specifications.

PERIFIX™ ONE Pediatric Epidural Catheter

Indications for Use: The PERIFIX™ ONE Pediatric Catheter is intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery for pediatric patients within the subgroups of Child (2 to 12 years of age) and Adolescent (12 to 21 years of age). Routes of Administration include epidural and perineural (peripheral nerve block) with a duration of use no longer than 72 hours.

Contraindication: Known hypersensitivity to one or more materials employed

Materials Used: PA, PUR, Yellow 138

NOTES:

- For the 20 Ga. catheter, the catheter has been tested for flow rates up to 35 mL/hr.
- For the 24 Ga. catheter, the catheter has been tested for flow rates up to 10 mL/hr.

Flow rates outside this range may not meet performance specifications.

PERIFIX™ Epidural Catheter

Indications for Use: The PERIFIX™ catheters are regional anesthesia catheters intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery as well as labor and delivery. Routes of administration are epidural. The catheters may remain indwelling for up to 72 hours.

Contraindication: Known hypersensitivity to one or more materials employed

Materials Used: PA with Tungsten Stripe, Blue Ink (Cobra PA Blue VP BB-02-02), PEBAX

Catheter Connector

for use with 18 - 24 Ga. PERIFIX™ Catheters

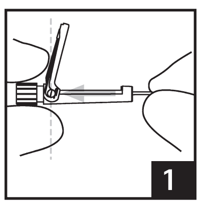
Indications for Use: A connection device used by physicians to provide various anesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anesthetics. The connector is used in conjunction with the catheter for continuous administration of anesthetic fluids.

Contraindication: Known hypersensitivity to one or more materials employed

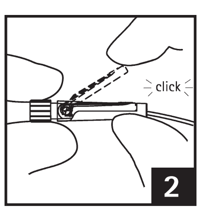
Materials Used: PP, TPE

Instructions for Use: Use Aseptic Technique.

1. Ensure that connector is in the open position by verifying that the top hinged piece can move freely away from main body of connector. Insert the proximal end of catheter into the distal end of connector. Advance catheter into the compression sleeve of the connector until it cannot be advanced any further (approx. 3 cm).

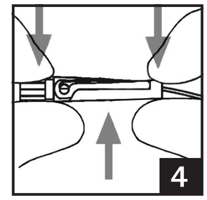


   WARNINGS:
   - DO NOT ATTACH ANY ANESTHETIC FLUID ADMINISTRATION DEVICES TO CONNECTOR IF REPLACEMENT STERILITY CAP IS MISSING, ASSUME THAT THE CATHETER CONNECTOR HAS BEEN CONTAMINATED AND REPLACE CONNECTOR.
   - DURING CONNECTION TO A CATHETER CONNECTOR, THE CATHETER MAY NOT BE FULLY INSERTED INTO THE CONNECTOR RESULTING IN THE POTENTIAL FOR CATHETER OCCLUSION OR LEAKAGE OF ANESTHETIC AGENT INTENDED FOR DELIVERY TO THE PATIENT VIA THE CATHETER. REOPEN AND REINSERT CATHETER. DURING MANIPULATION OF THE CONNECTOR WHEN ATTACHING ANESTHESIA DELIVERY DEVICE, THE CONNECTOR MAY BE INADVERTENTLY UNLOCKED, ALLOWING CATHETER TO COME LOOSE FROM THE CONNECTOR RISKING CONTAMINATION OF THE PROXIMAL END OF THE CATHETER, AND/OR INTERRUPTION OF ANESTHETIC DELIVERY.
2. Depress top hinged piece of connector until it clicks into place. There should be an audible “click” when this action is completed successfully.



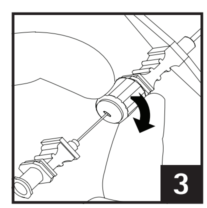
   WARNING: ENSURE CONNECTOR DOES NOT BECOME UNLOCKED DURING MANIPULATION WHICH COULD RESULT IN FLUID INTERRUPTION OR CONTAMINATION.
3. Remove plastic sterility cap and attach anti-bacterial filter or PERIFIX™ 0.2 µm filter (fluid retention is approximately 0.2 mL) or anesthetic administration device.

   CAUTION: DO NOT WET PERIFIX™ 0.2 µm FILTER WITH DISINFECTANTS CONTAINING ALCOHOL AS THIS MAY RESULT IN CRACKS IN THE FILTER HOUSING.
4. To open the connector, firmly hold connector with two fingers on each side. Press firmly on both sides of the connector, flexing downward as if you are trying to snap the connector in half.



ESPOCAN Docking System

1. After identification of the epidural space attach Docking System device onto the hub of epidural needle and rotate it in a clockwise direction until slight resistance is felt.
   NOTE: Do not tighten Docking System fully at this point. It should sit loosely on hub of epidural needle. If fully tightened, it will not be possible to introduce and advance the spinal needle.
2. Insert spinal needle through epidural needle and perform dural puncture. The spinal needle should be introduced until the spinal needle hub contacts the Docking System, or until CSF flow is identified upon removal of the spinal needle stylet.
   WARNINGS:
   - ESPOCAN SETS WITH DOCKING SYSTEM MUST NOT BE USED WITHOUT DOCKING SYSTEM BECAUSE SPINAL NEEDLE WILL BE TOO LONG (TIP TO TIP PROTRUSION) IN THIS CASE AND INADVERTENT PUNCTURE OF VENTRAL SIDE OF DURAL SAC MAY OCCUR.
   - IF BLOOD IN THE CSF CONTINUES TO BE SEEN AFTER REMOVAL OF STYLET, WITHDRAW THE NEEDLE AND RETRY AT A DIFFERENT INTERVERTEBRAL SPACE.
   - IF NO CSF IS OBSERVED, ROTATE THE NEEDLE TO ALL FOUR QUADRANTS AND CAREFULLY ASPIRATE UNTIL CSF IS VISIBLE. IF THIS PROCEDURE DOES NOT SHOW ANY FLOW OF CSF, REPEAT THE SPINAL/LUMBAR PUNCTURE
   - IF PARESTHESIA OCCURS AFTER REACHING THE SUBARACHNOID SPACE, THE NEEDLE SHOULD BE SLIGHTLY WITHDRAWN.
   - IF PARESTHESIA OCCURS DURING INJECTION, THE NEEDLE SHOULD BE REPOSITIONED PRIOR TO CONTINUING THE INJECTION.
3. After a successful puncture, fix spinal needle in epidural needle by twisting Docking System in a clockwise direction until it stops. Spinal needle is fixed and secure against inadvertent needle displacement. It is still possible to rotate spinal needle.



4. Fill 5 mL plastic procedural syringe with spinal anesthetic mixture. Attach syringe to the spinal needle and inject anesthetic mixture.
5. Twist Docking System counterclockwise to disconnect it from hub of epidural needle. Spinal needle and Docking System can now be withdrawn from epidural needle.
6. Remove spinal needle and Docking System then introduce epidural catheter through epidural needle using the thread assist guide. The guide will increase longitudinal stability of the catheter.
   CAUTION: DO NOT WITHDRAW CATHETER THROUGH NEEDLE BECAUSE OF THE DANGER OF SHEARING OR KINKING.
7. Aspirate and administer additional epidural anesthetic as needed.

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SPINOCAN® and PENCAN® Spinal Needles

Spinal Needles with Pencil Point and Quincke bevel configuration (see unit label for needle length, gauge size, and bevel configuration)

Indications for Use: The PENCAN and SPINOCAN Spinal Needles, with or without introducer, are intended for the injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management or to facilitate CSF sample collection for diagnostic purposes (lumbar puncture). The needles are intended for use in any target population with consideration given to the anatomy of the patient.

Contraindication: Known hypersensitivity to one or more materials employed

Materials Used: Stainless Steel, Nickel plated Brass, PC, PP and Epoxy Resin

Instructions for Use: Use Aseptic Technique.

1. Optimize position of the patient for spinal/lumbar puncture and injection.
2. Identify relevant anatomic landmarks around the puncture area.
3. Select and prepare insertion site per institutional protocols.
4. For kits containing drugs, shake and inspect ampuls. Prepare drugs for use by standing ampuls upright in circular depressions in the tray.
   CAUTION: IF CRACKED, CLOUDY OR UNDERFILLED, DO NOT USE AMPUL(S).
5. Initial skin puncture may be performed with introducer needle. If introducer needle is used, advance spinal needle and stylet through the introducer needle.
6. Perform spinal/lumbar puncture with spinal needle and stylet.
   WARNING: DO NOT UTILIZE NEEDLE IF IT BENDS OR TIP BECOMES DAMAGED. NEEDLE WITH DAMAGED TIP INCREASES THE RISK OF POST DURAL PUNCTURE HEADACHE DUE TO EXTENDED PERFORATION OF DURA MATER. DO NOT APPLY EXCESSIVE FORCE DURING NEEDLE ADVANCEMENT, NEEDLE MAY BEND OR EVENTUALLY BREAK.
7. Remove stylet from the spinal needle. Carefully check for the presence of cerebrospinal fluid (CSF).
   WARNINGS:
   - IF BLOOD IN THE CSF CONTINUES TO BE SEEN AFTER REMOVAL OF STYLET, WITHDRAW THE NEEDLE AND RETRY AT A DIFFERENT INTERVERTEBRAL SPACE.
   - IF NO CSF IS OBSERVED, ROTATE THE NEEDLE TO ALL FOUR QUADRANTS AND CAREFULLY ASPIRATE UNTIL CSF IS VISIBLE. IF THIS PROCEDURE DOES NOT SHOW ANY FLOW OF CSF, REPEAT THE SPINAL/LUMBAR PUNCTURE.
   - IF PARESTHESIA OCCURS AFTER REACHING THE SUBARACHNOID SPACE, THE NEEDLE SHOULD BE SLIGHTLY WITHDRAWN.
   - IF PARESTHESIA OCCURS DURING INJECTION, THE NEEDLE SHOULD BE REPOSITIONED PRIOR TO CONTINUING THE INJECTION.

Spinal Procedure:

- **When performing Spinal Anesthesia** - Inject the drug according to the manufacturer's instructions. Withdraw spinal needle and cover the puncture site with sterile dressing.
- **When performing Lumbar Puncture** - Take CSF sample for diagnosis, withdraw spinal needle, and cover the puncture site with sterile dressing.

Epidural Needles

Indications for Use: The needles are intended for use in epidural anesthesia and caudal block for administration of local anesthetic into the epidural space or for placement of an epidural catheter.

Contraindication: Known hypersensitivity to one or more materials employed

Materials Used: Stainless Steel, PC, UV Adhesive

WARNING: TAKE CARE TO AVOID ACCIDENTAL NEEDLESTICK INJURIES.

Instructions for Use: Use Aseptic Technique.

1. Optimize position of the patient during puncture and injection.
2. Identify landmarks and the puncture area.
3. Select and prepare insertion site per institutional protocols.
4. For kits containing drugs, shake and inspect ampuls. Prepare drugs for use by standing ampuls upright in circular depressions in the tray.
   CAUTION: IF CRACKED, CLOUDY OR UNDERFILLED, DO NOT USE AMPUL(S).
5. After complete injection, either withdraw the needle and cover the puncture site with sterile dressing or utilize for epidural catheter introduction.

See immediate container label for sterility, pyrogen claims, sterile barrier system, and storage conditions.

Not made with natural rubber latex.

Pictorials are for reference only.

Rx only

Single use

Do not resterilize

Do not use if package is damaged

NRFit is a registered trademark of GEDSA used with their permission.

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