NEXUS™ MIDLINE CT CATHETER INSTRUCTIONS FOR USE:

DESCRIPTION:
A family of peripherally inserted central catheters made from specially formulated biocompatible medical grade materials. Catheters are packaged in a tray with accessories necessary for a percutaneous micro introducer technique. The device is intended for short term (less than 30days) vascular access.

INDICATIONS FOR USE:
The NEXUS™ MIDLINE CT CATHETER is indicated for short-term (less than 30 days) peripheral access to the peripheral venous system for infusion, intravenous therapy and blood sampling. The NEXUS™ MIDLINE CT CATHETER is suitable for use with power injectors. For maximum flow rate and maximum pressure that can be used during power injection, please refer to the provided catheter information sheet.

IMPORTANT INFORMATION PERTAINING TO POWER INJECTION:
• Contrast media should be warmed to body temperature prior to power injection.
• Warning: Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
• Vigorously flush the NEXUS™ MIDLINE CT CATHETER using a 10cc or larger syringe and sterile saline solution prior to and immediately following the completion of power injection studies. This will ensure the patency of the catheter and prevent damage to the catheter. Resistance to flushing may indicate partial or complete occlusion.

COMPATIBILITY:
• Solutions with final glucose concentrations above 10 percent; Solutions with protein concentration above 5 percent;
• Continuous infusion of vesicants or corrosive fluids;
• Parenteral Nutrition;
• Solutions and medications with: inability to pass through the skin, make a small incision next to the anticipated insertion site to distend the vein.
• Attach sterile saline filled syringe to luer lock
• Insertion site:
  1. The basilic, median brachial, or cephalic vein may be catheterized. The basilic vein above antecubital fossa is the preferred site.
  2. The catheter tip location should be at or below the axillary line.

WARNING: Placement of a larger catheter at or below the antecubital fossa may result in the medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician’s experience and judgment in treating any specific patient.

WARNING: Do not use scissors to remove dressing. Recommended site for the device to be inserted is the basilic, cephalic, or brachial vein, distal to the shoulder. The basilic vein is preferred due to the vein diameter. The tip does not enter the central vasculature.

PREPARING CATHETER:
1. Preflush (prime) catheter, sidestep adapter, and needleless access port(s) with sterile Normal Saline Solution.
2. Attach sterile saline filled syringe to luer lock of sidestep adapter and flush adapter and catheter. Clamp sidestep extention and remove syringe. If using double lumen catheter, attach primed needleless access port to remaining extension. Attach a second sterile saline filled syringe to the needleless access port prior to clamping extension.

CAUTION: Never clamp on catheter styptic and stylet catheter damage may result.

STERILE EO:
Do not use catheter or accessories if package is opened or damaged.
Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:
• The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of this catheter or accessories.
• Contents sterile and non-pyrogenic in unopened, undamaged package.
• STERILIZED BY STERILX CROSS.

WARNING: Do not use syringe smaller than 20mL. Prolonged infusion pressure greater than 25psi may damage blood vessels or vein.

• Small syringes will generate excessive pressure and may damage the catheter. Ten (10cc) or larger syringes are recommended.
• Do not use sharp instruments near the extension lines or catheter lumen.
• Do not use scissors to remove dressing.
• Catheter will be damaged if clamps other than what is provided with this kit are used.
• Clamping of the tubing repeatedly in the same location will weaken tubing. Avoid clamping near the Luer(s) and hub of the catheter.

WARNING: Do not use catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.

Caution:
Catheter Occlusion
Catheter Erosion through the Skin
Exit Site Infection
Extravasation
Perforation of Vessels or Viscus
Spontaneous Catheter Tip Malposition or Retraction
Thromboembolism

Small vessel thrombosis
Vessel Erosion
Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Risks
Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

CONTRAINDICATIONS:
• The presence of device related infection, bacteremia, or sepsis is known or suspected.
• The patient’s vasculature size is insufficient to accommodate the size of the implanted device.
• The patient is known or is suspected to be allergic to materials contained in the device.
• There has been past irradiation of the expected in the catheter lumen will drop if the fluid level (allowing air entry) while clamping injection components, hold the assembly below the level of the patient’s heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection components, hold the assembly below the level of the patient’s heart before removing the injection caps.
• Do not advance the guidewire or catheter if resistance is encountered.
• Do not insert or withdraw the guidewire forcefully from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or sheath/dilator and guidewire must be removed together.
• Federal Law (USA) restricts this device to sale by or on the order of a physician.
• This catheter is for single use only, do not reuse. Reuse of catheter may result in cross-contamination, plastic degradation, catheter rupture, etc.

DIRECTIONS FOR MODIFIED Seldinger INSERTION:
• Use only guidewire with the tip terminated in either the basilic, cephalic, or brachial vein, distal to the shoulder. The basilic vein is preferred due to the vein diameter. The tip does not enter the central vasculature.

WARNING: Do not use a syringe smaller than 20mL. Prolonged infusion pressure greater than 25psi may damage blood vessels or vein.

WARNING: Do not use catheter or accessories if any sign of product damage is visible.

Failure to ensure the patient's vasculature size is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

• The patient’s vasculature size is insufficient to accommodate the size of the implanted device.

• Warning:
• Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.

• To prevent accidents, assure the security of all caps and connections prior to and between uses.

• Use only luer-lock (threaded) connectors with this catheter.

• Accessories to be used in conjunction with this catheter should utilize luer-lock connections.

• Repeated over tightening of luer lock connections, syringes, and caps will reduce connector life and could lead to potential connector failure.

• The maximum pressure or pound per square inch (psi) of the power injector utilized should not exceed 500 psi.

INSERTION SITES:
• The basilic, median brachial, or cephalic vein may be catheterized. The basilic vein above antecubital fossa is the preferred site.

Note: Midline catheters are peripheral infusion devices with the tips terminated in either the basilic, cephalic, or brachial vein, distal to the shoulder. The basilic vein is preferred due to the vein diameter. The tip does not enter the central vasculature.

PREPARATION CATHETER:
1. Preflush [prime] catheter, sidestep adapter, and needleless access port(s) with sterile Normal Saline Solution.

Cautions:
Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:
Vascular Thrombosis
Implantation Site
Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.

Caution:
Do not use scissors to remove dressing. Recommended site for the device to be inserted is the basilic, cephalic, or brachial vein, distal to the shoulder. The basilic vein is preferred due to the vein diameter. The tip does not enter the central vasculature.

WARNING: Placement of a larger catheter at or below the antecubital fossa may result in the medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician’s experience and judgment in treating any specific patient.

Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

CONTRAINDICATIONS:
• The presence of device related infection, bacteremia, or sepsis is known or suspected.
• The patient’s vasculature size is insufficient to accommodate the size of the implanted device.
• The patient is known or is suspected to be allergic to materials contained in the device.
• There has been past irradiation of the expected in the catheter lumen will drop if the fluid level (allowing air entry) while clamping injection components, hold the assembly below the level of the patient’s heart before removing the injection caps.
• Do not advance the guidewire or catheter if resistance is encountered.
• Do not insert or withdraw the guidewire forcefully from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or sheath/dilator and guidewire must be removed together.
• Federal Law (USA) restricts this device to sale by or on the order of a physician.
• This catheter is for single use only, do not reuse. Reuse of catheter may result in cross-contamination, plastic degradation, catheter rupture, etc.

DIRECTIONS FOR MODIFIED Seldinger INSERTION:
• Use only guidewire with the tip terminated in either the basilic, cephalic, or brachial vein, distal to the shoulder. The basilic vein is preferred due to the vein diameter. The tip does not enter the central vasculature.

WARNING: Do not use a syringe smaller than 20mL. Prolonged infusion pressure greater than 25psi may damage blood vessels or vein.

WARNING: Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:
Vascular Thrombosis
Implantation Site
Do not use the catheter if there is any evidence of mechanical damage or leaking. Ten (10cc) or larger syringes are recommended.

Do not use sharp instruments near the extension lines or catheter lumen.

Do not use scissors to remove dressing.

Catheter will be damaged if clamps other than what is provided with this kit are used.

Clamping of the tubing repeatedly in the same location will weaken tubing. Avoid clamping near the Luer(s) and hub of the catheter.

Examine catheter lumen and extension(s) before and after each infusion for damage.

Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.

To prevent accidents, assure the security of all caps and connections prior to and between uses.

Use only luer-lock (threaded) connectors with this catheter.

Accessories to be used in conjunction with this catheter should utilize luer-lock connections.

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sheath/dilator is fully inserted. 

7. Loosen locking collar of sideport and withdraw stylet back beyond the point where the catheter is to be trimmed by at least 3 cm (1 in), trim catheter to length determined by marked guidewire.

Caution: Never attempt to cut stylet.

Caution: Always withdraw stylet back beyond the tip of the catheter prior to insertion.

8. Once proper catheter length and stylet position has been achieved, tighten locking collar to keep stylet in place. 

9. Remove dilator from sheath.

10. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein. 

11. Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful)

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

12. The distal tip should be positioned at or below the axillary line.

Caution: Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use the serrated forceps, use only the in-line clamp(s) provided.

13. Remove the stylet by applying gentle pressure with one hand above the insertion site while grasping the stylet with the other hand and slowly pulling back with a constant motion. Remove sideport adaptor and replace with primed needless access port. Attach saline filled syringe to needless access port, aspirate lumen and then irrigate with saline. Remove syringe prior to clamping extension.

Caution: If difficulty and/or bunching of the catheter lumen are experienced while removing the stylet, additional flushing of the catheter may be helpful. The catheter may need to be repositioned to allow for removal of the stylet.

Caution: Do not attempt to reinsert stylet once it has been withdrawn.

Caution: Never leave stylet in place after catheter insertion; injury may occur. Remove both stylet and sideport adapter after insertion.

14. Attach syringe(s) to extension(s) and open clamp(s). Blood should aspirate easily. If excessive resistance to blood aspiration is experienced, the catheter may need to be repositioned to obtain an adequate flow.

15. Once adequate aspiration has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.

Caution: Small syringes will generate excessive pressure and may damage the catheter. Ten [10cc] or larger syringes are recommended.

16. Remove the syringe(s) and close clamp(s). Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use.

17. Confirm and document proper tip placement, midlines should be correctly positioned in the target vein.

Caution: Failure to verify catheter placement may result in complications.

Note: If there is no blood return, verify catheter position before use.

CATHETER SECUREMENT AND DRESSING: 

• The insertion site and external portion of the catheter should always be covered with a protective dressing.

• Cover the exit site with an occlusive dressing according to the facility policy.

• Record catheter type, length, catheter lot number, and tip position on patient’s chart.

POWER INJECTION PROCEDURE

- Remove the injection/needleless cap from the NEXUS™ MIDLINE CT CATHETER.

2. Using a 10cc or larger syringe(s), aspirate catheter lumen(s) to assure patency and remove heparin (if heparin is used for your lock solution). Discard syringe(s).

3. Attach a 10cc or larger syringe filled with sterile normal saline and vigorously flush the catheter with the full 10cc of sterile normal saline. Warning: Failure to ensure patency with NEXUS™ MIDLINE CT CATHETER, should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

Warning: Alcohol should not be used to soak or moisten the NEXUS™ MIDLINE CT CATHETER because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Warning: Aprotinin and polyethylene glycol containing solutions should not be used with the NEXUS™ MIDLINE CT CATHETER, as these may cause failure of the device.

Note: If resistance is felt - STOP. Retape the catheter and apply a warm compress to the extremity for 20-30 minutes.

5. Remove resolution procedures. If further difficulty is encountered, follow institutional policy for further intervention.

6. Apply pressure, if necessary, until bleeding stops and dress site following institutional policy.

Note: Inspect catheter and measure length. It must be equal to baseline measurement taken when the catheter was inserted.

Note: After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

WARRANTY

Health Line International Corp. WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.