I.V. CATHETER WITH CHECKVALVE AND NEEDLEGUARD

INSTRUCTIONS FOR USE

DESCRIPTION: Each Secure I.V.® with checkvalve and needleguard consists of four separate components: (1) special sterile cap, (2) protective packaging guard, (3) color-coded catheter hub with integral checkvalve, (4) needle hub and needleguard assembly. The catheter hub, needle hub and needleguard as packaged are properly sealed for insertion.

Secure I.V.® with checkvalve and needleguard is designed to prevent exposure to blood. The catheter’s packaging identifies its gauge, length, and material. The plastic needle hub is color coded to identify the gauge size of the catheter.

INDICATIONS: Secure I.V.® with checkvalve and needleguard is designed for single use only. A properly placed Secure I.V.® device provides peripheral access to the vein or artery per CDC guidelines.

CONTRAINDICATIONS: This device is not designed, sold, or intended for use except as indicated.

PRECAUTIONS: Secure I.V.® with checkvalve and needleguard is sterile and pyrogen free unless unit package is opened or damaged.

To fully protect against accidental needlesticks, clinician must follow instructions for use and be inserviced in proper product use.

Never advance needle inside catheter once the needle has been retracted or withdrawn. If venipuncture is unsuccessful, discard both needle and catheter in proper sharps container.

To avoid catheter damage or loss during intermittent therapy, use a 1" or shorter hypodermic needle through an injection cap, (heparin lock). A 25 gauge needle is recommended with a maximum 21 gauge needle size. Do not insert a needlesyringe into the catheter hub without first attaching an injection cap.

When removing catheter or changing dressing, do not use scissors to cut tape. Extreme care must be taken not to cut the catheter. Removal should be undertaken by trained personnel.

During catheter insertion, maintenance, and removal refer to the appropriate institutional, OSHA, and CDC guidelines. See, for instance, “Guideline for Prevention of Intravascular Device-Related Infections”, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE, Atlanta, GA 30333. www.cdc.gov/nicido/hip/i/v/v.htm; 1998.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

PROCEDURE: Because of the risk of blood contact, follow universal precautions during I.V. placement.

1. Select and prepare site per hospital protocol using aseptic technique. Apply tourniquet.

2. Remove the protective packaging from the catheter assembly, retaining the special sterile protective cap for later use (step 10). Ensure the needle hub assembly is positioned at the maximum forward travel point. The needle tip should be visible clear of any imperfections and should extend past the end of the catheter. The bevel of the needle should be facing upward. (Fig.1)

3. Using the thumb and second finger, hold the device on both sides of the ribbed needle hub while the index finger rests against the catheter hub. (Fig.2)

4. Insert the needle into the vein at the appropriate angle, watching for a blood return in the flashback chamber to confirm venous access.

5. Once venous access has been confirmed, the tourniquet may be released.

6. Holding the device stable with your finger against the catheter hub, thread the catheter forward into the vein. (Fig.3) As you thread the catheter retract the needle hub backwards.

CAUTION: DO NOT REINSERT NEEDLE INTO CATHETER AT ANY TIME. The needle could shear the catheter resulting in a catheter embolus.

7. When insertion is complete, grasp the front portion of the needle hub and finish retracting it to the back of the needle guard. An audible and tactile click indicates it is securely locked, giving proper sharp’s protection.

8. To release the needle guard from the catheter, hold the catheter hub securely in place and twist the needleguard counterclockwise one-half turn. (Fig.4)

9. Upon removal of the needleguard the internal checkvalve of the catheter will remain closed, preventing any blood spillage or blood flow.

10. Attach an I.V. set, injection cap or special protective cap (included) and apply dressing according to institution protocol.

CAUTION: FOR PROTECTION DURING INTERMITTENT USAGE, EMPLOY ONLY THE SPECIAL STERILE CAP PROVIDED. Other caps may activate the checkvalve.

11. Dispose of needleguard in proper sharps container.

12. Device is activated by engaging a male Luer fitting.