Instructions for Use

TRACE™

Central Venous Catheter (CVC) Kits

Description:

The TRACE™ Central Venous Catheters (CVC) are sterile, single use range of short-term catheters designed to facilitate infusion therapy in a critical care environment. They are available in four configurations; single, double, triple and quad lumen and in a variety of lengths. The multi lumen variants provide dedicated lumens for infusion therapy, pressure monitoring and venous sampling. The CVCs are packaged as kits along with components and accessories considered necessary for their percutaneous insertion. All CVC kits are sterilized by ethylene oxide.

Indications for Use:

The TRACE™ Central Venous Catheters are indicated to permit short term (<30 days) central venous access. Uses include, but are not limited to the following:

- Monitor of central venous pressure;
- Continuous or discontinuous venous transfusion / infusion;
- Blood sampling.

The Catheter is surgically penetrated using the Seldinger Technique into any of the 3 puncture points depending on the clinical requirement. The puncture points are:

1. Internal jugular vein; or
2. Subclavian vein; or
3. Femoral vein.

Contraindications:

- Long term use (>30 days)
- Infection or cut wound around the puncture area.
- Dysfunction of blood coagulation.
- During the anticoagulant treatment.
- Symptoms of inadaptability to puncture operation

Warnings:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in loss of blood and delay to the procedure.
2. Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance. Blood and other foreign material can collect in the inner parts of the product which cannot be removed.
3. Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
4. Rx Only. The products must be used by trained physicians
5. Connections should only be made with devices compliant to ISO 80369-7
6. Some disinfectants used at catheter insertion site contain solvents which can weaken the catheter material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.
    a. Do not use acetone on catheter surface.
    b. Do not use alcohol to soak catheter surface or allow alcohol to dwell in a catheter lumen to restore catheter patency or as an infection prevention measure.
    c. Do not use polyethylene glycol containing ointments at insertion site.
    d. Take care when infusing drugs with a high concentration of alcohol.
    e. Allow insertion site to dry completely prior to applying dressing.

Precautions:

1. Aseptic techniques must be used wherever possible, especially during removal from packaging.
2. The connection should be hand tightened, but not over tightened as that can lead to cracks which may cause an embolism.
3. Check products carefully to ensure there is no entrapped air which can lead to an embolism
4. Verify the position of the catheter tip by X-ray
5. Ensure the connection is secure as insecure connections can lead to air in the system which can cause an embolism

Instructions for Use:

Preparation

1. The selection of the insertion site and the appropriate catheter type and length is at the sole discretion of the physician.
2. Flush each of the catheter lumens with saline expelling all the air then clamp the catheter extensions to ensure that the saline does not inadvertently drain from the catheter. Use the integral clamps provided.

Insertion

3. Administer sufficient local anaesthetic to completely anaesthetise the insertion site.
4. Insert the introducer needle into target vein. Aspirate to ensure proper placement.
5. Insert the flexible end of the guide wire into the introducer needle and advance the guide wire with forward motion into the target vein. Use ultrasonic to ensure a correct insertion, if necessary.
6. Remove the needle leaving the guidewire in the vessel and enlarge the cutaneous puncture site with a scalpel.
7. Thread the vessel dilator over the proximal end of the guide wire and dilate the subcutaneous tissue and vein wall to facilitate the insertion of the catheter.
8. Remove the vessel dilator leaving the guide wire in place.
9. Open the distal extension clamp and thread the catheter over the proximal end of the guide wire.
10. Ease the catheter through the subcutaneous tissue and into the target vein.
11. Once proper placement is confirmed, remove the guidewire and close the clamp.
12. Attach a syringe to each of the extensions in turn. Open the clamp and blood should aspirate easily. If the lumens exhibit excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.
13. Once adequate aspiration has been established, each lumen should be locked according to standard hospital protocols.
14. Close the clamp and attach the injection cap(s) onto the extension line female luer(s).

Catheter Fixed and Wound Dressing

The catheter should be fixed and the insertion site dressed according to standard hospital protocols.

“WARNING: Do not suture the catheter tubing itself.”

If the catheter is not to be used immediately, follow standard hospital protocols for catheter locking.

Infusion

1. The locking solution should be removed from each lumen prior to instigating infusion and aspiration should be based on standard hospital protocol.
2. Check all connections carefully before initiating any infusion. Infusion protocols should be determined by physician prescription.

Blood Sampling

When taking blood samples through the catheter temporarily shut off the other lumen(s) through which solutions are being infused.

Daily Care

Daily care of the puncture site should be undertaken according to standard hospital protocols.

Catheter Removal

1. Carefully remove all securement devices and dressings, and then slowly withdraw the catheter.
2. Apply pressure to the exit site for approximately 10-15 minutes or until bleeding stops.
3. Apply dressings in accordance with standard hospital protocols.

Disposal:

Catheters can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal

Potential Complications / Adverse Effects

The clinical benefit of the use of CVC's must be evaluated against the recognized risks and complications of the procedure which include but are not limited to:

- Infection, necrosis of the puncture point.
- Air embolism.
- Pneumothorax and / or hemopneumothorax.
- Infection of the puncture channel
- Subcutaneous hematoma.
- cardiac tamponade secondary to vessel, atrial, or ventricular perforation
- pleural (i.e., pneumothorax) and mediastinal injuries
- catheter embolism
- catheter occlusion
- thoracic duct laceration
- bacteremia
- septicemia
- thrombosis
- inadvertent arterial puncture
- nerve injury
- hematoma
- hemorrhage
- fibrin sheath formation
- exit site infection
- vessel erosion
- catheter tip malposition
- dysrhythmias
- extravasation

Warranty and Limitations

Products are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code

	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit


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