Anesthesia, Surgery, and Post-Operative Recovery

- Risks Normally Associated with Local or General
- Retroperitoneal Bleed
- Pneumothorax
- Mediastinal Injury
- Laceration of Vessels or Viscus
- Laceration of the Vessel

POTENTIAL COMPLICATIONS:
- Factors may prevent proper device stabilization
- Suffered episodes of venous thrombosis or
- Lumen catheter indicated for use in attaining

INDICATIONS FOR USE:
- Than 30 days) vascular access only and should
- The maximum recommended infusion rate is
- Jugular, femoral or subclavian vein as required.
- and central venous pressure monitoring.
- Power injection procedure.
- For evaluating the health status of a patient as it
- Contrast media implies the catheter’s ability to
- Catheter tip displacement.
- Indicate partial or complete catheter occlusion.
- Resistance to flushing may
- Patency of the catheter and prevent damage to
- Infusion
- CT
- Air embolism and remove the catheter.
- Should be stopped immediately.
- Pertains to a power injection procedure.
- Does not imply the
- Contrast media implies
- with the procedure, but does not imply the
- Precipitation could occur.
- Recirculation in femoral catheters was
- In the rare event that a hub or connector
- or on the order of a physician.
- Do not re-sterilize the catheter or accessories
- Do not advance the guidewire or catheter if

CONTRAINDICATIONS:
- This catheter is intended for short-term (less than 30 days) vascular access only and
- When the device of related infection, bacteremia, or sepsis is known or
- When the patient’s body is insufficient to accommodate the size of the implanted device.
- If the prospective placement site has been previously irradiated.
- If the prospective placement site has previously suffered an episode of venous thrombosis or vascular surgical procedures. If local tissue factors are noted, the catheter procedure should be stopped immediately.

WARNINGs:
- In the rare event that a hub or connector separation occurs at any component of the catheter, insert or use, take all necessary steps and
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcefully, or in any component of the catheter which may break or unseal. If the guidewire becomes damaged, the catheter and guidewire must be removed together.
- Federal Law (USA) restricts the device to sale, lease or order by or on the order of a physician.

This catheter is for Single Use Only.

Do not re-sterilize the catheter or accessories by any method.

IMPORTANT INFORMATION PERTAINING TO SITE INJECTION

- Contrast media should be warmed to body temperature (37°C) prior to injection failure.
- Do not use sharp instruments near the extension tubing or catheter lumen.
- Do not use ascises 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 may weaken tubing. Avoid clamping near the hubs and lumen of the catheter.
- Examine catheter lumen and extensions before each treatment with the catheter.
- To prevent accidental extravasation, secure the catheter at all times.
- Reuse may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages, losses, and expenses, and claims for re-instatement of this catheter or accessories.
- Contents sterile and non- pyrogenic in unsheathed, undamaged package.
- STERILE [E0]
- Do not use catheter or accessories if any sign of product damage is visible.
- Failure to warn patients in the catheter prior to power injection studies may result in catheter failure.
- Vigrously flush the catheter using a 10cc or larger syringe and sterile normal saline prior to and immediately following injection 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 catheter occlusion.
- Do not proceed with the power injection study if the catheter is not patent.

Catheter Precautions:
- Do not use sharp instruments near the extension tubing 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 may weaken tubing. Avoid clamping near the hubs and lumen of the catheter.
- Examine catheter lumen and extensions before each treatment with the catheter.
- To prevent accidental extravasation, secure the catheter at all times.
- Use the only lumen marked “property marked” for power injection of contrast media.
- Do not exceed the maximum flow rate of 5cc/sec.
- Warning: Power injector machine pressure setting failure may not prevent over pressurization of the included catheter.
- Warning: Exceeding the maximum flow rate of 5cc/sec may result in catheter failure and /or catheter tip displacement.
- Warning: The indication of power injection catheter for use is inverted to the power injection device. Without the procedure, but does not imply the appropriateness of the procedure for use in a particular patient. A suitably trained clinician is required for the health and safety of the patient as it pertains to a power injection procedure.
- Warning: If local pain, swelling, or signs of infection are noted, the catheter procedure should be stopped immediately.

POSSIBLE COMPLICATIONS:
- Air Embolism
- Bleeding
- Injury to the Nerves
- Infection
- Cardiac arrhythmias
- Thrombosis
- Problems with the Skin
- Catheter Kinking
- Occlusion
- Catheter Related Infection
- Thrombosis
- Misalignment
- Catheter Related Thrombosis
- Hemorrhage
- Hemothorax
- Hemoptysis

ATTACHMENT TO Implanted Device
- Insertion, Maintenance, and Removal of the Catheter
- Failure to verify catheter placement

INSERTIONS SITES

Caution: Left placed insertion in particular, may present anesthetic challenges due to the potential that the internal jugular vein can be punctured by the inferior vena cava and the left brachiocephalic vein, especially with a 14 gauge needle. Therefore, the physician should always follow the initial insertion of the catheter and confirm proper placement prior to use.

Caution: The patient should be in a modified Trendelenburg position, with the upper clavicle exposed and the head hyperextended to the side opposite the insertion area. Slight head elevation may be inserted between the clavicle and the first rib in the first ribs.

Caution: Have patient lift his head from the bed to the define the sternumsternal muscle.

Note: The position of the subclavian vein, which is posterior to the clavicle, to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the first rib and the anterior border of the first rib.)

FEMORAL VEIN

Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmias throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Catheter arrhythmias may result if guidance is allowed to pass into the right atrium. The guidance should be held securely during this procedure.

Caution: When introducer needle is used, do not guide needles against other tendons around the catheter to avoid possible severing of guiding sheath.

Caution: Use only Luer Latch (threaded) Connector with this catheter in order to avoid inadvertent disconnection.

Caution: Repeated tightening of bloodline connections will help reduce catheter life and could lead to potential connector failure.

Caution: Do not use infected or unsanitary gloves to connect and withdraw the catheter.

Note: For femoral placement, monitor patient for hematothrexaemia, infection, and bleeding. Pressure applied should be left in place for longer than three days.

Caution: Use only Luer Latch (threaded) Connector with this catheter in order to avoid inadvertent disconnection.

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Caution: Do not use infected or unsanitary gloves to connect and withdraw the catheter.

Note: For femoral placement, monitor patient for hematothrexaemia, infection, and bleeding. Pressure applied should be left in place for longer than three days.
Warning: Failure to ensure patency of the catheter prior to infusion studies may result in catheter failure.

4. Detach syringe.

5. Attach the power injection device to the catheter per manufacturer's recommendations.

Warning: Do not power inject through a catheter that exhibits signs of clave-first rib compression or pinch-off, as it may result in catheter failure.

Warning: Always use connector tubing between power injector syringe and catheter. Do not attempt to connect power injector directly to the catheter. Damage may result.

6. Complete power injection study taking care not to exceed the flow rate limits.

Warning: Exceeding the maximum indicated flow rate of 5cc/sec may result in catheter failure and/or catheter tip displacement.

Warning: Power injection machine or pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may result in catheter failure.

7. Disconnect the power injection device.

8. Flush the catheter with 10cc of sterile normal saline, using a 10cc or larger syringe.

9. Look the lumens marked “power injectable” per institutional protocol for central lines.

10. Replace the injection/needleless cap on the catheter tip.

Caution: Only clamp catheter with in-line clamps and caps exposed for access by staff.

Caution: Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

If a leak is found, the catheter should be clamped immediately.

Removal of the catheter must be performed by a physician's instructions.

INFLUENCING FACTORS

The heparin solution must be removed from infusion lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol.

Before infusion begins all connections should be examined carefully.

Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.

If a leak is found, the catheter should be clamped immediately.

Removal of the catheter must be performed by a physician's instructions.

Caution: Only clamp catheter with in-line clamps and caps exposed for access by staff.

Caution: Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

If a leak is found, the catheter should be clamped immediately.

Caution: Increased recirculation will occur if the arterial and venous lines are reversed during a simulated dialysis treatment at 500 mL/min flow rate. Fluid used was 15% Saline and 45% Glucose with a viscosity similar to blood (3 to 4 centipose).

CENTRAL VENOUS PRESSURE MONITORING (CVP)

Note: CVP Monitoring should not be performed with all relevant regulatory requirements.

1. Cut sutures from suture wing. Follow hospital protocol to remove the sutures.

2. Withdraw catheter through the exit site.

Note: Patients must not swim, shower, or soak the catheter site while healing.

3. Attach a syringe containing heparin solution to the female luer of each extension.

4. Attach a sterile injection cap onto the female luer of each extension.

5. Reposition patient.

6. Have patient cough.

7. Reposition catheter.

8. Apply an occlusive dressing.

9. Place a sterile occlusive dressing over the female luer of each extension.

Caution: Due to the risk of exposure to HIV, human immunodeficiency Virus, or other bloodborne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

Sterile technique should always be strictly adhered to.

Patient benefit should be assured to prevent catheter failure.

Caution: Due to the risk of exposure to HIV, human immunodeficiency Virus, or other bloodborne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

Sterile technique should always be strictly adhered to.

Clinical examination of a central catheter exit site should be examined carefully.

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