Subcutaneous Hematoma
Septicemia
Risks Normally Associated with Local or General
Right Atrial Puncture
Mediastinal Injury
Laceration of the Vessel
Hemothorax
Exsanguination
Air Embolus
suffered episodes of venous thrombosis or
be allergic to materials contained in the device.
This device is also contraindicated:
CONTRAINDICATIONS
This device is intended for short-term (less than 30 days) vascular access only and should not be used for any purpose other than

DESCRIPTION
The 7.5-T catheter lumens are manufactured from radiopaque thermoplastic material which provides increased patient comfort while providing excellent biocompatibility. The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required.

INDICATIONS FOR USE:
The catheter is intended to be inserted in the
jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is

IMPORTANCE INFORMATION PERTAINING TO POWER INJECTION
Contrast media must be warmed to body
temperature (37°C) prior to power injection.

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 those supplied with the catheter are used. Clamp the catheter tubing with in-line clamps during the procedure.
Examine catheter lumen and extensions before and after each treatment for damage.
To prevent accidents, assure that all caps and bloodline connections are secured and tightened.
Use only Luer Lock threaded Connectors with this catheter in order to avoid inadvertent disconnection of catheter lumen.
Do Not exceed the maximum flow rate of 50cc/sec.

WARNING:
Failure to use proper equipment may result in catheter failure.

WARNING:
Use only the lumen marked "power injectable" for power injection procedures.

WARNING:
Do Not exceed the maximum flow rate of 50cc/sec.

WARNING:
Exceeding the maximum flow rate of Catheter results in catheter failure / catheter tip disconnection.

WARNING:
The indication of power injection may be diminished if the catheter does not withstand the procedure, but this does not imply the appropriateness of the procedure itself. The physician may choose a different catheter tip based on the patient’s size and condition.

WARNING:
If local pain, swelling, or signs of infection are noted after catheter insertion, the patient should be reevaluated for catheter tip disconnection.

WARNING:
In the rare event that a hub or connector separator from any component during insertion or use, take all necessary steps and report to the manufacturer any air embolism and remove the catheter.

WARNING:
Do not advance the guidewire or catheter if there is any resistance to advancement.

WARNING:
Do not insert or withdraw the guidewire forcibly from any component. The wire may break. If the guidewire becomes damaged, the catheter and guidewire must be discarded together.

WARNING:
Federal Law (USA) restricts the device to use by or on the order of a physician.

This catheter is for Single Use Only.

Urged catheter or saline, then clamp catheter extensions to assure that saline is not used directly from the infusion pumps. Use clamps provided.

Caution: Do not clamp the lumens of the catheter for any purpose other than when the catheter is being removed, and do not confine the arm or joint to which the catheter is secured.

Restriction of hand, arm, and joint movements during catheter placement should be examined carefully.

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

Caution: Only clamp catheter lumen in-line clamps provided.
INFUSION

- The hepatic solution must be removed from infusion litter 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.

Caution: Only clamp catheter with in-line clamps provided with the catheter.

- Necessary removal action must be taken prior to the continuation of the infusion treatment.

Note: Excessive blood loss may lead to patient death.

Caution: Increased recirculation will occur if the arterial and venous lines are reversed during a dialysis treatment.

Average Recirculation Rates (15.5F)

<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Recirculation %</th>
<th>Reverse Recirculation %</th>
</tr>
</thead>
<tbody>
<tr>
<td>24cm</td>
<td>0.96</td>
<td>2.60</td>
</tr>
<tr>
<td>115cm</td>
<td>0.40</td>
<td>12.53</td>
</tr>
<tr>
<td>52cm</td>
<td>0.29</td>
<td>20.48</td>
</tr>
</tbody>
</table>

Infusion treatment should be performed under physician's (or equivalent health professional's) guidelines.

POWER INJECTION PROCEDURE

1. Remove the injection / needleless cap from the catheter.
2. Using a 10cc or larger syringe aspirate for adequate blood return to remove locking solution and to assure patency. Exudate should be clear and free of clots.
3. Attach a 15cc or larger syringe filled with sterile normal saline and vigorously flush the catheter with the full 15cc of sterile normal saline.

a.) Warning: Failure to ensure patency of the catheter prior to power injection 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 contains signs of clavicle-first rib compression or pinch-off, as it may result in catheter failure.

Warning: Always use connector tubing between appropriate power injector 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 5 cc/sec may result in catheter failure and/or catheter tip displacement.

Warranty: Power injection machines or pressure limiting failure may prevent over-pressurization of the 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. Lock the lumen marked "power injectable" per institutional protocol for central lines.
10. Replace the injection/needleless cap on the catheter.

CENTRAL VENOUS PRESSURE MONITORING (CVP)

- CVP Monitoring is intended to be performed through the distal purple lumen.
- Use your institution's protocols for central venous pressure monitoring procedures.
- Prior to conducting central venous pressure monitoring:
  1. Ensure proper positioning of the catheter tip.
  2. Flush catheter vigorously with sterile normal saline.
  3. Ensure the pressure transducer is at the level of the right atrium.
- It is recommended that a continuous infusion of saline (0.9%) is maintained through the catheter while measuring CVP.

Warning: CVP Monitoring should always be used in conjunction with other patient assessment methods for obtaining cardiac function.

Warning: CVP Monitoring should not be performed during hemodialysis, hemoperfusion, or apheresis.

Note: Only a physician familiar with the appropriate techniques should attempt the following procedures.

CATHETER PERFORMANCE

- If the catheter is not to be used immediately for treatment, follow the suggested catheter patency protocols.
- To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.
- Follow hospital protocol for heparin concentration.
- Drain catheter into syringes, corresponding to the amount designated on each extension. Assure that the syringes are free of air.
- Remove injection cap from the extension.
- Attach a syringe containing heparin solution to the female luer of each extension.
- Open extension clamps.
- Aspire to insure that no air will be forced into the patient.

Note: Each lumen should be completely filled with a heparin to ensure effectiveness.

- Close extension clamps.

Warning: Extension clamps should only be open for appropriate blood return and dialysis treatment. If clamps are opened, blood may enter the distal portion of the catheter, ultimately resulting in a thrombus.

- Remove syringes.

Warning: Extensive clamps.

- Attach a sterile injection cap onto the female luer of the extensions.
- In most instances, no further heparin is necessary for 48-72 hours, provided the lumens have not been aspirated or flushed.

SITE CARE

- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extensions, clamps, and caps exposed for access by staff.
- Alcohol or alcohol-containing antiseptics (such as chlorhexidine gluconate) may be used to clean the catheter/skin site.

Alternate compatible solutions include:

- Betadine® Solution (10% Povidone Iodine)
- Hydrogen Peroxide
- 0.05% Sodium Hypochlorite
- Antimicrobial Ointments and Creams (Mupirocin, Polymyxin)
- Silver Iodocine Cream 1%
- Silver Iodine Patch

- Solutions should be allowed to completely dry before applying occlusive dressing.
- Wound dressings must be kept clean and dry.

Caution: Patients must not swim, shower, or soak dressing while bathing.

- If profuse pericarditic or accidental wetting compromises adhesion of the dressing, the nurse or nursing staff must remove the dressing under sterile conditions.

CATHETER REMOVAL

- If a catheter culture is not present, follow the hospital protocol for removal of skin sutures.
- Withdraw the catheter through the exit site.
- Apply pressure to exit site for approximately 15 minutes or until bleeding stops.
- Apply dressing in a manner to promote optimal healing.

INSUFFICIENT FLOWS:

The following may cause insufficient blood flows:

- Occluded proximal holes due to clotting or fibrin occlusion.
- Occlusion of the side holes due to contact with vein wall.

Solutions include:

- Chemical intervention utilizing a thrombolytic agent.

MANAGEMENT OF ONE WAY OBSTRUCTIONS:

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This is usually caused by tip malposition.

One of the following adjustments may resolve the obstruction.

- Reposition catheter.
- Reposition patient.
- Have patient cough.
- Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try and move the tip away from the vessel wall.
- Never forcibly flush an obstructed lumen. If any lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider using appropriate agents or thrombolytic agents to dissolve the clot.

INFECTION

- Due to the risk of exposure to HIV / Human Immunodeficiency Virus or other blood borne diseases, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.
- Infection technique should always be strictly adhered to.
- Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.
- If a fever occurs in a patient with a catheter in place, take a minimum of two blood cultures from a site distant from catheter exit site. If both cultures is positive, the catheter must be removed immediately and the appropriate antibiotic therapy initiated. Wait 48 hours before catheter replacement. Insertion should be made on opposite side of original catheter exit site, if possible.

Warranty: Medcomp warrants that this product is manufactured according to applicable laws and regulations. WARRANTY

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp reserves the right to modify its products or contents in accordance with said changes.

Medcomp is a registered trademark of Medical Components, Inc.

SYMBOLS TABLE

* This symbol is in accordance with ISO 15223-1.
** FDA guidance Use of Symbols in Labeling.

Note: Temperature symbols: °C is only applicable to devices with temperature indication.

REFERENCES:


FLOWS RATING TESTS REPRESENT OPTIMUM LABORATORY CONDITIONS

Average Recirculation Rate for power injection of contrast media.

1 Internal catheter pressure during power injection with injector safety cut-off at 254 psi, using contrast media with 11.8 cP viscosity.

2 Max burst pressure in the static burst pressure failure point of the catheter. Catheter failure was also observed at these pressures.

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Rev. 2/18 A

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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>WARRANTY</th>
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<tbody>
<tr>
<td>Keep Dry</td>
<td>Do Not Use</td>
</tr>
<tr>
<td>Non-sterile</td>
<td>Keep Away from Sunlight</td>
</tr>
<tr>
<td>Sterile</td>
<td>Do Not If Package is Damaged</td>
</tr>
<tr>
<td>On/Off</td>
<td>Expiry Date</td>
</tr>
<tr>
<td>Batch/Lot</td>
<td>Do Not Resterilize</td>
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<table>
<thead>
<tr>
<th>Catalogue Number</th>
<th>Caution, central Accompanying Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult Instructions for Use</td>
<td>Prescription Use Only</td>
</tr>
<tr>
<td>European Temperature Limits</td>
<td>European Temperature Limits</td>
</tr>
<tr>
<td>European Temperature Limits</td>
<td>Master Representative in the European Community</td>
</tr>
</tbody>
</table>

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