Retroperitoneal Bleed

Contents sterile and non-pyrogenic in

The patient should be in a modified

Subclavian Artery Puncture

Hemorrhage

Examine catheter lumen and extensions

Vascular Thrombosis

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

WARNING:

In the rare event that a hub or
cuff becomes separated from the component
during insertion or use, take all necessary steps
to prevent blood loss or air embolism and remove
catheter.

Do not advance the guidewire or catheter if
unnecessary resuscitation is encountered.

Do not insert or withdraw the guidewire/
styrette forcibly from any component.
The wire may break or unravel. If the guidewire
becomes damaged, the guidewire along with
the introducer needle, Vascu-Shath®
introducer, styllet, or styrette must be
removed together.

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

This catheter is for Single Use Only.

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

Re-Use may lead to infection or injury.

The manufacturer shall not be liable for
any damages caused by error or re-
sterilization of this catheter or
accessories.

Contents sterile and non-pyrogenic in
sterile packaging.

STERILIZED BY ETHYLENE OXIDE

Air Embolism

Bacteremia

Bacterial Pneumonia

Cardiac Arrhythmia

Cardiac Tamponade

Central Venous Thrombosis

Endocarditis

graft selection

Embolization

Remborement

Laceration of the vessel

Lumens Thrombosis

Medication and I.V.

Perfusion of the Vessel

Pneumothorax

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

May inject cap can be treated by

Do not clamp arterial extension when styrette
is in catheter.

To prevent accidental, assure the security of
all caps and bloodline connections prior to
use and between treatments.

Use only Laser Lock® (hydroyte) Connectors
with this catheter.

Repeated over tightening of bloodlines,
evenges, and caps will reduce catheter
durability and could to potential connector
failure.

Always tape lany locks to bloodlines
during treatment. Do not use lany locks against
arterial disconnection.

WARNING:

Use of laser lany locks will be against sale
by or on the order of a physician.

Insertion Site:

Warning: Laser shock damage is possible
when using the lany lock mechanism.

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when using the lany lock mechanism.

In the event of catheter damage or
unsuccessful insertion, the catheter should be
removed. The patient should be prepared for
treatment for damage to adjacent vascular
structures.

Patient requiring ventilator support are at
increased risk of pulmonary complications
from subclavian vein cannulation, may
cause complications.

Extended use of the subclavian vein may be
associated with subclavian vein stenosis.

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Sliding catheter tunneling sleeve over the
catheter making certain that the sleeve
covers the arterial lobe of the catheter.
Insertion into the catheter hub and
create a short subcutaneous tunnel. Do
not pull catheter through the Y-hub of the
tunnel should be made with care in order to
to prevent damage to adjacent vascular
structures.

Do not over-expand subcutaneous
stellen during tunneling. Over-expansion may
delay/prevent cuff in-growth.

6. Lead catheter into the tunnel gently. Do
not pull or insert the catheter during
resuscitation, as this may prevent the
right atrium. The guidewire should be held
securely to prevent the cuff from the catheter.

Caution:

Do not pull tunnel end at an angle.
Keep your hand straight to prevent damage
to catheter tip.

4. Make a small incision at the exit site
on the chest wall approximately 1 cm
below the clavicle. Make a second incision
above the first incision and parallel to the
first in the at the insert site. Make incision at the
exit site wide enough to accommodate the cuff,
approximately 1 cm.

5. Insert the guidewire into the
tunnel gently. Do not pull or
insert the catheter during
resuscitation, as this may prevent
the guidewire from entering
the right atrium. The guidewire
should be held securely to prevent the
cuff from the catheter.

6. Lead catheter into the tunnel gently. Do
not pull or insert the catheter during
resuscitation, as this may prevent
the guidewire from entering
the right atrium. The guidewire
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cuff from the catheter.

7. Irrigate catheters in saline solution to
ensure the guidewire is in place. Do
not pull or insert the catheter during
resuscitation, as this may prevent
the guidewire from entering
the right atrium. The guidewire
should be held securely to prevent the
cuff from the catheter.

8. #3: Select and mark the long subcutaneous
tunnel. Do not pull or insert the
catheter during
resuscitation, as this may prevent
the guidewire from entering
the right atrium. The guidewire
should be held securely to prevent the
cuff from the catheter.

9. Confirm the proper guidewire length
should be made with care in order to
prevent damage to adjacent vascular
structures.

10. Remove the guidewire catheter from the
right atrium. The guidewire should be held
securely to prevent the cuff from the
catheter.

11. Make any adjustments to catheter under
fluoroscopy. The venous distal tip should
be positioned at the level of the caval atrial
junction or into the right atrium to ensure
adequate blood flow.

12. Close the extension clamps, remove the
yumpes and place an injection cap on
every luer lock connector. Avoid
embolism to any extension clamps at
closed at all times, when not in use and by
on the patient when irrigating the catheter
with saline prior to each use. With
each clamp to clamping connections, purge
air from the catheter and all connecting
tubing and caps.

13. To maintain patency, a heparin lock must
besetQuery

14. Once the catheter is locked with heparin,
close clamps and install injection caps
onto the extensions‘ female luer locks.

15. Confirm proper tip placement with
fluoroscopy. The distal venous tip should
be positioned at the level of the caval
atrial junction or into the right atrium to ensure
adequate blood flow.

16. Insert the guidewire catheter into
vein. Carotid arhymnias may result
if the guidewire is allowed to pass into
the right atrium. The guidewire should be
held securely to prevent the cuff from the
 catheter.

17. Do not leave vessel dilator(s) in place
as an indwelling catheter to avoid possible
evessel wall perforation.

18. Thread the proximal end of the
guidewire through the catheter nut and
into the right atrium to ensure
adequate blood flow.

19. Once the guidewire extends through the
right atrial lumen, clamp the guidewire to
ensure adequate blood flow.

20. To maintain patency, a heparin lock must
be queried on both lumens. Failure to do
so may result in air embolism.

21. Once the catheter is locked with heparin,
close clamps and install injection caps
onto the extensions‘ female luer locks.

22. Confirm proper tip placement with
fluoroscopy. The distal venous tip should
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atrial junction or into the right atrium to ensure
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atrial junction or into the right atrium to ensure
adequate blood flow.
Hemodialysis should be performed under 

Caution: Care must be taken when using sharp needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

Note: If using StatLock® for catheter securment, ensure the area where the Lock Right® Adapter will be on the patient with alcohol. Remove the backing of one side of the StatLock® patch and position on patient. Once positioned, remove the remaining protective backing. Apply gentle pressure on the pad to assure adherence. Push the collar section of the Lock Right® Adapter into the receiving groove of the StatLock® pad. Repeat for second adapter.

24. Cover the exit site with occlusive dressing.

25. Catheter must be secured for entire duration of implantation.

26. Record catheter length and catheter lot number on patient’s chart and check catheter position routinely.

REMEDIATION/TREATMENT

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

- Before dialysis begins all connections to catheter and extracorporeal circuits 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.

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

Note: Excessive blood loss may lead to patient shock.

- Remedial action should be performed under physician’s instruction.

REHEPARIZATION

- If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.

- To maintain patency between treatments, a heparinized flush must be created in each lumen of the catheter.

- Follow hospital protocol for heparin concentration.

1. Draw heparin into two syringes, corresponding to the amount designated on the arterial and venous extensions. Ensure the syringes are free of air.

2. Remove injection caps from the extensions.

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

4. Open extensions clamps.

5. Aspirate to insure that no air will be forced into the patient.

6. Inject heparin into each lumen using lock box technique.

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

7. Close extension clamps.

Caution: Extension clamps should only be adhesively secured, flushing, and dialysis treatment.

8. Remove syringes.

9. 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 extension clamps, caps exposed for access by staff.

- Wound dressings must be kept clean and dry.

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

- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.

CATHETER PERFORMANCE

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Palpate the catheter exit tunnel to locate the exit site. If blood culture is positive, the exit site should be examined carefully.

2. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.


4. Make a 2cm incision over the parallel to the catheter.

5. Dissect down to the cuff using blunt and sharp dissection as indicated.

6. When visible, grasp cuff with clamp.

7. Clamp catheter between the cuff and insertion site.

8. Insert catheter through incision in the tunnel.

9. Remove remaining section of catheter i.e. portion in tunnel through the exit site.

Caution: Do not pull dilatation of catheter through incision as contamination of wound may occur.

10. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.

11. Suture incision and apply dressing in a manner to promote optimal support.

12. Check catheter integrity for tears and measure catheter when removed. It must be equal to the length of catheter when it was inserted.

FLOW/PRESSURE DATA

VENOUS ONLY

<table>
<thead>
<tr>
<th>FLOW RATE</th>
<th>PRESSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>250 mL/min</td>
<td>140 mmHg</td>
</tr>
<tr>
<td>200 mL/min</td>
<td>130 mmHg</td>
</tr>
<tr>
<td>150 mL/min</td>
<td>120 mmHg</td>
</tr>
<tr>
<td>100 mL/min</td>
<td>115 mmHg</td>
</tr>
<tr>
<td>50 mL/min</td>
<td>110 mmHg</td>
</tr>
</tbody>
</table>

FLOW RATE TESTING REPRESENTS OPTIMUM LABORATORY CONDITIONS

CATHETER REMOVAL

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

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SYMBOL TABLE

- **Manufacture**
- Keep Dry®
- Non-sterile *
- Keep away from sunlight®
- Sterilized Using Ethylene Oxide®
- Do Not Use If Package Is Damaged
- Use-by Date
- Do Not Resterilize®
- Batch/Lot Number *
- Catalogue Number *
- Caution, consult Accompanying Documents*
- Do Not Re-use
- Consult Instructions for Use *
- Rx Only

*Prescription Use Only ***

*This symbol is in accordance with ISO 15223-1.

** FDA guidance Use Symbols in Labeling.

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** FDA guidance Use Symbols in Labeling.

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