Guideline

Guideline Title: Femostop II Plus: Femoral Compression Device use in ICU

Summary: The femostop II plus femoral compression device may be used to achieve haemostasis and to prevent associated complications post removal of arterial sheaths, venous sheaths or Intra Aortic Balloon (IAB) catheter sheath.

Approved by: Director of ICU

Publication (Issue) Date: January 2015

Next Review Date: January 2018

Replaces Existing Policy/ Guideline: ICU Guideline for the use of Femostop femoral compression device


Background
The Femostop II plus, femoral compression device is used to achieve haemostasis after removal of femoral arterial or venous lines/sheaths and to prevent associated complications.

1. Introduction:
The risk addressed by this policy:
Patients who have removal of a femoral arterial or venous sheath will have a femostop II plus device used, where appropriate, to achieve haemostasis and to provide patient safety and comfort.

The Aims / Expected Outcome of this guideline:
To achieve haemostasis after removal of femoral arterial or venous lines/sheaths and to prevent associated complications.

Related Standards or Legislation
- NSQHS Standard 1 Governance
- National Standard 4 Medication Safety

Related Policies
ICU Guideline_Systems_Cardiothoracic_Intra-aortic_balloon_pump
2. Policy Statement

- All care provided within the Liverpool Hospital will be in accordance with infection control guidelines, manual handling guidelines and minimisation and management of aggression guidelines.
- The femostop II plus device is only to be applied by trained and accredited nursing and medical staff.
- The femostop II plus device may not be suitable for very obese patients, as adequate haemostasis may not be achieved. Digital compression may be more appropriate for these patients as directed by medical staff.
- Application and removal of the femostop II plus device must be documented on the ICU flow chart in the special observations section, including time, duration of application, and degree of pressure.
- Circulatory observations of the affected limb must be documented on the ICU flow chart including colour, sensation, movement, capillary return and temperature.
- Compression times expressed in this guideline can be altered depending on the condition of the artery, catheter size and anticoagulant therapy used.
- The operator must remain with the patient while high pressure is used to totally occlude the artery for the first 2 to 3 minutes and pedal pulses are absent. Pedal pulses should be present at all other times.
- An accredited and trained assistant is required to position the device and assist until the sheath is removed.
- Bed rest must be maintained for a minimum of six hours post arterial sheath removal.
- **Patient to remain in bed for 24 hours post removal of sheath of Intra Aortic Balloon (IAB) catheter as risk of retroperitoneal bleed is high.**
- The femostop II plus compression device should not be applied for longer than 2 hours.
- The femostop II plus arch should be cleaned as per hospital infection control policy.
- The belt and dome are disposable.

3. Principles / Guidelines

**Removal of venous / arterial sheath:**

**Equipment:**
- Dressing pack
- Blue sheets
- Extra large gauze or combine packs
- Suture cutter
- 2% Chlorhexidine in 70% Alcohol solution to clean the site
- 0.9% Sodium Chloride if required for flushes
- Femostop II disposal device, arch, dome and manometer
- Sterile gloves, protective eye wear and long sleeve gown
- Transparent occlusive dressing
- Doppler with gel
- 1 mg of IV atropine if required for vasovagal episodes
- 500 mL crystalloid solution as required for fluid bolus
- Lignocaine 1-2% for infiltration around sheath exit site for local Anaesthetic – this is very rarely required.

**Prior to procedure:**
- Explain the procedure to the patient including the application of pressure by the femostop II plus device, length of time that it will be in place, and activity
restrictions during and following the procedure. Make sure the patient understand the rationales for all preparations.

- Prior to the application of the femostop II plus the following must be attended:
  - Heparin infusion ceased at least 2-4 hours before arterial device removal.
  - Patent IV access.
  - Cardiac monitoring in progress.
  - Ensure that the patient is haemodynamically stable.
  - Ensure arterial blood pressure is visible or NIBP is set every 3 minutes while the arterial device/sheath is removed and the femostop II plus device is applied and until haemostasis is achieved. NIBP should be attended every 15 minutes for the whole time that the femostop II plus device remains in situ.
  - Baseline blood pressure and neurovascular observations, including colour, sensation, movement, capillary return and pulses, in both legs are assessed and documented in the ICU flow chart.
  - Mark the location of the peripheral pulses with a marker pen.
  - If haematoma is present prior to the application of the femostop II plus device, outline the parameters with a marker pen.

- Check dome and connections of the femostop II plus device to make sure there are no defects that could affect the product performance or procedure.

- Ensure PT, APTT and platelets are within acceptable parameters prior to arterial sheath removal:
  - Normal values for PT = 10.5-13.5 seconds, APTT = 23-36 seconds, PLT = 150-400 x 10^9/L.
  - If these parameters are outside normal limits then the ACT (Activated clotting time) should be checked prior to removal. The ACT machine is located in the Coronary care unit or in Cardiac Cath Lab. The acceptable ACT is <150 if the patient is on antiplatelet drugs and <180 if they are not on antiplatelet drugs. This has to be confirmed and documented by the medical officer prior to removal of the sheath.

Procedure:

- Lay the patient flat and position the femostop II plus device belt distributed equally under the patient’s hips in line with the puncture site.
- Attach dome to the compression arch, do not remove the covering on the sterile surface of the dome, and lock by rotating dome clockwise.
- Check all connections to make sure that they are secured and that there are no defects.
- Clean the area with 2% Chlorhexidine in 70% Alcohol solution and cut sutures.
- Inject local anaesthetic and give light sedation if required (rarely required).
- Remove cover from dome and position the centre of dome slightly superior (1 cm) and medial (1 cm) to skin puncture site.
- Ensure hub of sheath clears edge of dome rim. If not, withdraw sheath slightly.
- Fully compress sidearm levers on compression arch to allow belt to be threaded.
- Adjust the belt to a snug fit. The arch should be level and sit squarely across groin area. Failure to adjust belt properly will result in extremely high inflation pressures being required to achieve haemostasis (i.e. >200mmHg).
- Attach pump to dome using a stopcock if desired. If using the stopcock, ensure that the handle is accessible.
- If the patient needs analgesia, administer the prescribed dose (rarely required).

To remove venous sheath:

- Inflate the dome to 20-30mmHg with belt loose. Tighten the belt while removing the venous sheath and increase the pressure if necessary to control bleeding.

To remove arterial sheath:

- Inflate the dome to 10-20mmHg above the patient’s SBP while removing the sheath.
Removal should be commenced while pressure is low and should be completed by the time the pressure reaches 60-80mmHg. Slight bleeding at this stage is expected and acceptable.

For IABP sheath removal, once the arterial sheath is removed, let bleeding occur for 1 to 2 seconds in case of any clots that could have been formed around the IAB sheath.

- Continue to increase the pressure (to 10-20mmHg above SBP) until haemostasis is achieved for approximately 2 to 3 minutes. **Do not exceed 3 minutes.** During this time pedal pulses are absent due to the artery being totally occluded.
- To maintain the pressure required during this period and while reducing it, ensure that the stopcock/valve is switched off so that there is less chance of the dome deflating unexpectedly.
- While maintaining haemostasis lower the pressure enough to locate a strong pedal and/or posterior tibial pulse.
- Maintain that pressure for 30 minutes unless bleeding occurs.
- If bleeding, re inflate to initial haemostasis pressure for a further 2-3 minutes then try decreasing again.
- Lower the pressure in 15mmHg increments every 15 minutes until a pressure of 40mmHg is reached if haemostasis is maintained throughout.
- Ensure that the skin does not become trapped as the dome folds and pressure is decreased.
- Maintain a pressure of 40mmHg for 30 minutes then completely deflate the dome.
- Ask the patient to cough to ensure haemostasis before final removal of the device.
- After removal the femoral compression device arch should be cleaned as per hospital infection control policy.
- The belt and dome are disposable.

**Removal of IABP sheath**

- Check coags, PT / INR /APPT, ensure that these are within the hospital’s normal ranges. Liverpool Hospital normal values for PT = 10.5-13.5 seconds, APTT = 23-36 seconds, PLT = 150-400 x 10^9/L. If these parameters are outside normal limits then the ACT (Activated clotting time) should be checked prior to removal. The ACT machine is located in the Coronary care unit or in Cardiac Cath Lab. The acceptable ACT is <150 if the patient is on antiplatelet drugs and <180 if they are not on antiplatelet drugs. This has to be confirmed and documented by the medical officer prior to removal of the sheath.
- Must be attended by a Medical Officer.

Can be done in three ways:

- Removal of IABP and application of direct digital pressure by Medical Officer until restoration of haemostasis and then application of pressure dressing.
- Removal of IABP and application of femoral compression device, femstop II plus.
- Return to theatre for removal of non-percutaneous inserted balloons or for percutaneous balloons that are difficult to remove.

**Equipment**

- Dressing pack
- Blue sheets
- Extra large gauze or combine packs
- Suture cutter
- 2% Chlorhexidine in 70% Alcohol solution to clean the site
- 0.9% Sodium Chloride if required for flushes
- Femostop II plus disposal device, arch, dome and manometer
- Sterile gloves, protective eye wear and long sleeve gown
- Transparent occlusive dressing
Procedure to remove IABP sheath by a medical officer

- Observe universal precautions
- Explain procedure to the patient and their care after removal of IABP
- Assist the Medical Officer as instructed.
- Lay the patient flat.
- Put the IABP in “standby”.
- Medical Officer cleanses the area with 2% Chlorhexidine in 70% Alcohol solution and undoes the stitches.
- The tubing is then disconnected to allow passive deflation of helium from the intra-aortic balloon.
- Medical officer pulls the IABP out and observes for the presence of clots.
- Allows the site to bleed for 1-2 seconds to allow for the evacuation of any clots and reduce the risk of emboli.
- Control the bleeding and maintain haemostasis by using either of the following 2 methods:
  - Using the femostop II plus compression device.
  - Applying direct pressure for at least 20 minutes.
- If still bleeding, continue with manual pressure. Consider the application of femostop II plus device if available.
- After manual pressure apply transparent dressing and compression by combine and Elastoplast.
- Observe if still bleeding after four hours then continue with pressure dressing and for the sandbag to remain insitu. Instructions as per post removal of femostop II plus device.

Care of patient after IABP sheath removal

- Patient’s care over the next 24hrs is explained again.
- Observations of the IABP insertion site and limb observations are to be attended hourly for four hours, 2nd hourly for a further four hours, then fourth hourly thereafter.
- Patient may then have head of bed elevated no more than 30° in the first four hours, then slowly increase to 45°, if patient tolerates.
- Patient to remain in bed for 24hrs post IABP removal.

If the patient is sat up too high or allowed to get out of bed before the 24hrs then the risk of retroperitoneal bleed is very high.

Complications of IABP sheath removal

- Limb ischaemia.
- Local haematoma
- Arterial injury
- Retroperitoneal bleeding
- Excessive bleeding from insertion site.
- Thrombocytopenia.
- Thromboembolism.
- Immobility of balloon catheter.
- Balloon leak.
- Infection.
- Aortic dissection.
- Compartment syndrome may develop after IABP removal.
Observations while femostop II plus femoral compression device is in situ:
- HR, BP, RR, SpO₂, neurovascular limb observations (colour, sensation, warmth, movement, pulses, capillary return), puncture site for bleeding and/or haematoma formation.
- Observations are to be recorded in the ICU flow chart.
- The following regime is a guide:
  - Every 15 minutes for 1 hour.
  - Every 30 minutes for 2 hours.
  - Then hourly until femostop II plus device removed.
- Frequency of observations should be individualised based on the patient’s condition and risk category. There is no current strong evidence to determine best practice.

Nursing management post removal of femostop II plus device:
- Once haemostasis is achieved and femostop II plus device is removed, the insertion site is dressed with an occlusive transparent dressing to keep dry.
- Ensure the patient is comfortable.
- Head of the bed can be elevated to 30° for 1 hour, 45° for 1 hour then as desired.
- The puncture site and circulation should be monitored for 4 hours post removal of the femostop II plus device. See above for post removal of IABP sheath.
- Observations are to be recorded in the ICU flow chart.
- The following regime is a guide:
  - Every 15 minutes for 1 hour.
  - Every 30 minutes for 2 hours.
  - Then hourly for 4 hours.
- Observe for signs of vascular complications such as tenderness, presence of groin mass, pulsatility, presence of bruit, ischaemia, signs of leg ischaemia.
- If stable HR, BP, RR, SpO₂ can be attended every 4 hours depending upon patient’s diagnosis and other conditions for 24 hours post removal.
- Instruct the patient to inform nursing staff immediately of any obvious bleeding, sensation of wetness, burning or tearing at the puncture site. Or any other signs that are worrying the patient.
- Confirm with medical staff when and if their heparin should be re commenced.
- Patient to remain in bed for 24 hours post sheath or IABP catheter removal.

Contraindications:
- The femostop II plus compression device is not to be used on excessively obese patients as adequate haemostasis cannot be achieved. Digital compression must be used for these patients.

Complications and management:
- Vasovagal episode:
  - Decreased HR, decreased BP with possible loss of consciousness usually occurs because of pain and/or pressure at the sheath site.
  - If sustained, can be treated with 1 to 2 boluses of Atropine 500mcg to 1mg and/or 200-500mL fluid bolus.
  - Loosening of the belt.
  - Analgesia as required.
- Bleeding or haematoma:
  - While the femostop II plus device is insitu bleeding may occur because the dome has slipped out of position.
  - Reposition the dome and adjust belt if necessary.
  - If unable to see the bleeding site or reposition the femostop II plus device it is best to remove the femostop II plus device from the belt, quickly clean the area
with sterile gauze or combine pad and apply digital pressure proximal to the puncture site to achieve haemostasis. Call for assistance.

- Retroperitoneal bleed:
  - Patient to remain in bed and positioned as recommended post removal of the femostop II plus femoral compression device.
  - Patients that have an IABP catheter sheath removed have a high risk of retroperitoneal bleed therefore they need to be observed closely and strict bed rest for 24 hours after removal is essential.

4. Performance Measures

All incidents are documented using the hospital electronic reporting system: IIMS and managed appropriately by the NUM and staff as directed.

5. References / Links


Author: P. Nekic, CNE- ICU, reviewed by S.Shunker, CNC– ICU
Reviewers: Director-ICU, ICU – Staff Specialists, NM, CNE’s, CNS’s, Pharmacists.
Endorsed by: A/Prof M. Parr, Director- ICU
**Summary of the guideline**

**Procedure for removal of arterial or venous sheath**

- APTT, PT and platelets within acceptable limits. If abnormal check ACT.
- Documented request for removal.
- Pt to lie flat and position belt under the hips in line with the puncture site.
- Patent IV access, ensure monitoring.
- Ensure pt is haemodynamically stable.

**Venous Sheath**

- Inflate dome to 30mmHg with belt loose
- Tighten belt as sheath removed
- Increase pressure as required to control bleeding

**Arterial Sheath**

- Inflate dome to 20mmHg above SBP while removing sheath.
- Removal is achieved while pressure is low and completed when pressure is at 60-80mmHg.
- Continue to increase pressure until haemostasis.
- Maintain initial pressure for 2-3 mins when artery is occluded and pedal pulses absent. **Do not exceed 3 minutes.**

**Pressure reduction and maintenance of haemostasis**

- Reduce pressure to attain strong pedal pulse.
- Maintain that pressure for 30 mins.
- Lower pressure by 15mmHg every 15 mins until pressure of 40mmHg.
- Ensure skin does not become trapped as the dome folds and pressure is being released.
- Maintain 40mmHg pressure for 30 mins, and then completely deflate the dome.
- Ask patient to cough observing for bleeding.
- If not bleeding, remove the femstop pressure device.

**Femstop II Plus preparation**

- Remove cover from dome and position 1cm above and 1cm to the side of the puncture site.
- Ensure sheath hub is clear of dome rib, withdraw sheath slightly if required.
- Compress sidearm levers on compression arch, thread through belt for a snug fit.
- The arch should be levelled and sit squarely across groin area.
- Attach pump to the dome using a stopcock. Ensure the handle is accessible.

**Observations**

- Monitor HR, BP, RR, SpO₂, neurovascular limb observations (colour, warmth, sensation, movement, pulses, capillary return), puncture site (bleeding, haematoma).
- Every 15 mins for 1 hour.
- Every 30 mins for 2 hours.
- Hourly until removal of femstop pressure device.
- Record on ICU chart.

**If bleeding re occurs**

- Re inflate device to original haemostasis pressure.
- Keep the pressure for 2 mins.
- Commence reduction of pressure process as previously.