Ambulation and Discharge Recommendations

The following information are suggested guidelines, and should not be a substitute for physicians orders.

Patients who have undergone diagnostic angiography and have received a 6Fr ANGIO-SEAL Vascular Closure Device can safely and effectively ambulate in less than 20 minutes and be discharged one hour post ambulation1,2.

Patients receiving ANGIO-SEAL Vascular Closure Device following an interventional procedure using a 6F procedural sheath can be ambulated in approximately 1 hour3.

For patients who have undergone an interventional procedure using sheaths greater than 6F, post-procedure ambulation is at the discretion of the physician.

Activity and Ambulation

- The head of the bed may be elevated 15-45 degrees to increase patient comfort4-7.
- Have patient support the puncture site when coughing, sneezing or straining.
- Patient may ambulate and be discharged per physician's orders.

Discharge Information

Review the patient care instructions with the patient. The following guidelines are recommended:

- Patients may feel a "pea size" lump and or mild tenderness in the groin.
- Patients should avoid driving the day of discharge.
- Patients may take a shower.
- Patients should avoid baths, hot tub use or swimming until the puncture site is healed.
- For 48-72 hours, patients should refrain from lifting anything over ten pounds.
- Dressing change - the day after discharge, remove the dressing and gently clean the site with mild soap and water. Gently dry the site and cover with a bandage. Change dressing daily until the skin heals.
- Provide the ANGIO-SEAL Device Patient Guide and Information Card to the patient or family.
- Instruct the patient to carry the Patient Information Card for 90 days. After this time, the ANGIO-SEAL Vascular Closure Device components are absorbed8.
- Instruct patient to contact their physician who performed the procedure if the following symptoms occur:
  - Fever
  - Bleeding
  - Wound drainage
  - Rash
  - Persistent tenderness in the groin or swelling
  - Redness and/or warm to touch
  - Numbness or pain in the extremity when ambulating
Nursing Care and Patient Instructions

This nursing care guide is for health care professionals caring for patients that have received the ANGIO-SEAL Vascular Closure Device following an angiographic or interventional procedure. Please follow hospital accepted protocols for patient care. This guide is not a substitute for physician orders.

Patient Assessment Post Procedure

- Check femoral puncture site. Visualize the site and palpate as required to assess for:
  - Bleeding
  - Bruising/Hematoma
  - Swelling
- Assess presence and quality of distal pulses as compared to pre-procedure status. Use accepted hospital protocol for grading pulses.
- Inspect lower extremity for:
  - Color
  - Temperature
  - Sensation
- Check vital signs per hospital protocol.
- Keep puncture site clean and dry.

If Bleeding Occurs

Please follow hospital accepted protocols for patient care. This guide is not a substitute for physician orders.

Oozing - The procedure sheath has created a tissue tract to the artery and it may fill with blood and saturate the dressings.

Nursing Intervention

- Apply light manual pressure to the puncture site for approximately 2-3 minutes. Assess the source and intensity of bleeding along with the condition of the site (hematoma, bruising, etc.).
- Once hemostasis is assured, apply a sterile dressing using hospital accepted protocol.

Active Bleeding - This may present with pulsatile flow or enlarging hematoma.

Nursing Intervention

- Apply manual pressure using hospital accepted protocol.
- If head of bed is elevated, lower the head of the bed.
- Monitor vital signs.
- Once hemostasis is assured, apply a sterile dressing using hospital accepted protocol.
- Notify the physician of any change in the patient’s status.

Indications:

The ANGIO-SEAL Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis of the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8 F ANGIO-SEAL device and a 6 French or smaller procedural sheath for the 6 F ANGIO-SEAL device. The ANGIO-SEAL STS Plus, VIP and Evolution platform devices are also indicated for use to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to safely ambulate after sheath removal and device placement.

Important Safety Information:

Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation or edema. This device should only be used by a licensed physician (or other health care professional authorized by or under the direction of such physician) possessing adequate instruction in the use of the device, e.g., participation in an ANGIO-SEAL physician instruction program or equivalent.

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References

1. ANGIO-SEAL® VIP Instructions for Use, TMC600006628 Revision 2017-01.
2. ANGIO-SEAL® EVOLUTION Instructions for Use, TMC600006626 Revision 2017-01.

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