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IN THIS ISSUE

Adopting a Strategy of Early Ambulation and Same-Day Discharge for Atrial Fibrillation Ablation Cases

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The atrial fibrillation ablation procedure has become the most commonly performed EP procedure at our institution. The procedure is increasingly common for the management of paroxysmal atrial fibrillation and persistent atrial fibrillation, as well as post-ablation atrial tachycardia and flutter. For the purpose of this article, these are all included in "atrial fibrillation ablation". Due to the increased volume of these cases, an increase occurs in utilization of hospital resources such as inpatient beds, nursing staff, pain meds, etc. For the past several years, we have adopted a strategy of same-day discharge for some EP procedures. Patients undergoing new implants of a pacemaker, defibrillator, or CRT device are generally discharged home after 3-6 hours, and generator changes after 1-2 hours. Patients undergoing SVT ablation and right atrial flutter ablation are discharged after 4-6 hours as well. Approximately 60-65% of all device implants in the past year were successfully discharged on the same day at our facility. We have traditionally kept patients overnight who undergo a transseptal puncture, an 8 French

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Cover Story

Adopting a Strategy of Early Ambulation and Same-Day Discharge for Atrial Fibrillation Ablation Cases

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(Fr) arterial puncture, and those with multiple comorbidities. Recently, we have moved towards a strategy of same-day discharge for AF ablation patients. In this article, we discuss the aspects to successful same-day discharge for AF ablation patients.

Managing vascular access sites is a critical part of early ambulation and discharge. Our approach to vascular access has evolved significantly, driven by an effort to improve safety and efficiency. We have eliminated arterial access in most AF cases. All venous punctures are guided by vascular ultrasound. Access sites are limited to single site (usually right femoral), and 2-3 venous sheaths are introduced separated by approximately 1 cm in a cranial-caudal direction (Figure 3) Specifically, two 8.5 Fr SL1 sheaths and a short 8.5 Fr sheath are used to introduce an intracardiac ultrasound (ICE) catheter (CARTO SOUNDSTAR or ACUNAV Catheter, Biosense Webster, Inc., a Johnson & Johnson company). After transseptal access is achieved, we remove the ICE catheter and introduce a duodecapolar catheter through the same sheath, and position it into the coronary sinus with proximal electrodes around the tricuspid annulus. Additionally, one or two SL1 sheaths are placed for transseptal access, depending on user preference. These are used for introducing the ablation catheter (THERMOCOOL SMARTTOUCH SF Catheter, Biosense Webster, Inc., a Johnson & Johnson company) and mapping catheter (LASSO or PENTARAY Catheter, Biosense Webster, Inc., a Johnson & Johnson company). We perform either a single or double transseptal access for pulmonary vein isolation (PVI). Blood pressure is monitored non-invasively every 3 minutes, and end-tidal CO2 monitoring is performed continuously. Minimizing the number of punctures is helpful in reducing bleeding complications, as well as limiting the cost of vascular closure devices (VCD) used at the end of the case. We reintroduce the ICE catheter before concluding the case and examine for pericardial effusion. Two to three VCDs (Perclose ProGlide Suture-Mediated Closure System, Abbott Vascular) are used to allow immediate sheath removal in the EP lab prior to transfer to the PACU (Figure 4). Protamine is also administered in the EP lab; although with use of a VCD, this is optional. All patients are given 1% lidocaine or 0.5% bupivacaine in the access site. A two-hour bed rest is advised at an angle of 60 degrees (up immediately), with an additional two- to three-hour observation period before discharge home. In managing the vascular access in this manner, we have been able to reduce the risk of post-op bleeding, the need for additional pressure to achieve hemostasis with or without use of the FemoStop device (Abbott Vascular), and almost eliminate the incidence of severe vascular complications such as hematoma, pseudoaneurysm formation, and retroperitoneal hemorrhage.

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Foley catheter placement has been eliminated in most patients. The majority of the cases last between one to three hours, and patients are encouraged to void immediately before they are taken to the EP lab. We hope this will reduce the incidence of Foley-related complications such as UTI. It is important to monitor the time in the left atrium, as longer procedures result in more fluid infusion through the irrigated ablation catheter tip.

We use high-frequency ventilation (>25 respirations per minute with a tidal volume 200-250 ml). This has significantly improved the efficiency of the procedure due to increased catheter stability and effectiveness of lesions. Titrating lesions to achieve maximum efficacy is important. We also use CARTO VISITAG Module (Biosense Webster, Inc., a Johnson & Johnson company) settings (Max distance change 2-3 mm, Stability min time 3-5 sec, FOT 25%, Min Force 3 g) to allow for efficient and durable PVI. As changes in catheter or lesion settings (VISITAG) are adopted, the incidence of post-procedure chest pain and pericarditis should be monitored.

We carefully select patients who are eligible for same-day discharge. Usually these patients are younger and indicate a preference to be discharged. Patients who live more than 30 minutes away are kept for overnight observation.

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Figure 1: Front row, left to right: Elizabeth Kurzawa, RN; Gretchen Thomas, RCES; Candace Williams, RT(R), RCIS; Jeanette Duncan, RN; Miranda Dishon, RCES; Susan Silver, CRNA; Erin Gaudett, MA. Back row (L to R): Evan Giedrimas, MD; Dennis Langford, RT(R), RCES; Jarrod Bauldree, RCES; Thabet Alsheikh, MD, FACC, FHRS; Bill Huson, RN, RCES, CEPS; Michael Drlicka, RN, RCES; Sumit Verma, MD, FACC.

Figure 2: Baptist Heart & Vascular Institute at Baptist Hospital in Pensacola, Florida.

Early Ambulation

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Similarly, elderly or frail patients, those with multiple comorbidities, and those undergoing extensive ablation are monitored overnight. We recognize the small possibility of delayed tamponade post-AFib ablation; however, this does not change our strategy given the very infrequent occurrence of this problem. Patients completing the procedure after 1400 hours are generally excluded from same-day discharge. All patients are re-evaluated by the MD and discharged if ambulatory, without chest pain or nausea, and have eaten and voided. Patients receive a follow-up phone call the next day by our AFib Center's registered nurse coordinator.

A same-day discharge strategy for AF cases requires considerable institutional commitment. Patient safety is a major concern. However, we feel this is a reasonable strategy given our previous extensive experience and safety record with AF ablation. Possibly more than half of the patients undergoing AF ablation are candidates for same-day discharge. Careful involvement of all members of the AF care team is required as the patients go through AF treatment and follow-up. Patients have access to our AF coordinator during work hours and can speak to an on-call electrophysiologist at any time.

Although the initial impression is that the cost of supplies increases significantly using multiple VCD per case, our cost analysis has been favorable. In fact, there may be a small cost benefit associated with early ambulation and same-day discharge.

The majority of the cost savings are related to reduced hospital bed utilization. Additional cost savings are related to reduced nursing hours related to sheath removal in PACU, elimination of protamine in some cases and potential reactions to protamine, reduction in pain meds for back pain, and reduction of Foley-related complications. The case turnaround time is also favorably impacted by this strategy. Patient acceptance to this has been very positive, especially for patients who have a reference from having undergone previous procedures. This has allowed several beds per day to be available for other patients on the cardiac floor. We have used the figure of 8 stitch technique in the past for managing venous puncture sites; however, in my experience, this does not allow the degree of hemostasis and control over the puncture site that is required to safely manage AF patients.

VCDs have been shown to be safe and effective in reducing duration of bed rest and possibly complications. Early studies have evaluated early ambulation after cardiac catheterization using the Perclose ProGlide.[1] These studies have shown a favorable outcome in regards to time to ambulation (TTA) and time to discharge (TTD). The Perclose ProGlide was found to be safe and effective for femoral artery closure in patients who ambulate within 30 minutes after cardiac catheterization, resulting in improved patient satisfaction and substantial cost savings.[1] It was also recently shown to be safe and effective in venous punctures up to 24 French.[2]

The recently concluded AMBULATE study using the VASCADE MVP Venous Vascular Closure System (Cardiva Medical) evaluated its use in the AFib ablation population.[3] This prospective, multicenter, randomized study compared the VASCADE MVP 1:1 with manual compression. A total of 204 patients were studied in 13 sites. All patients had multiple (3 or 4) mid-bore (6-12 Fr inner diameter sheath) femoral venous access sites. The treatment group had all sites closed with the VASCADE MVP, while the control group had all sites closed using manual compression. Both cryo and radiofrequency energy sources were used. In the VCD arm, there was a 64% reduction in median TTA, 63% increase in patient satisfaction for duration of bed rest, 3.9-hour median reduction in TTA, and 58% fewer patients received opioids.[3]

Studies have also shown the feasibility of same-day discharge for AF ablation patients, although these studies did not use a VCD to help facilitate early ambulation. Deyell et al[4] reported a series of 1579 patients undergoing AF ablation. Of these, 1407 (89.1%) were discharged on the same day of ablation. In the remaining 172 (10.9%), the common reasons for failure of same-day discharge were access site problems (39/172, 22.7%), intraprocedural complications (34/172, 19.8%), and anesthesia-related problems (29/172, 16.9%).[4] Notably, age, prior procedures, and comorbidities did not influence the ability to achieve same-day discharge.[4]

In summary, early ambulation and same-day discharge of AF ablation patients is possible for carefully selected patients in centers performing a high volume of these cases. The use of VCD has been shown to improve patient satisfaction as well as allow early ambulation and discharge. When carefully applied, this strategy has the potential to reduce complications, decrease resource utilization, and allow cost savings, while improving patient satisfaction. As more experience is gained, we will be able to further identify which patient subgroups benefit the most. ■

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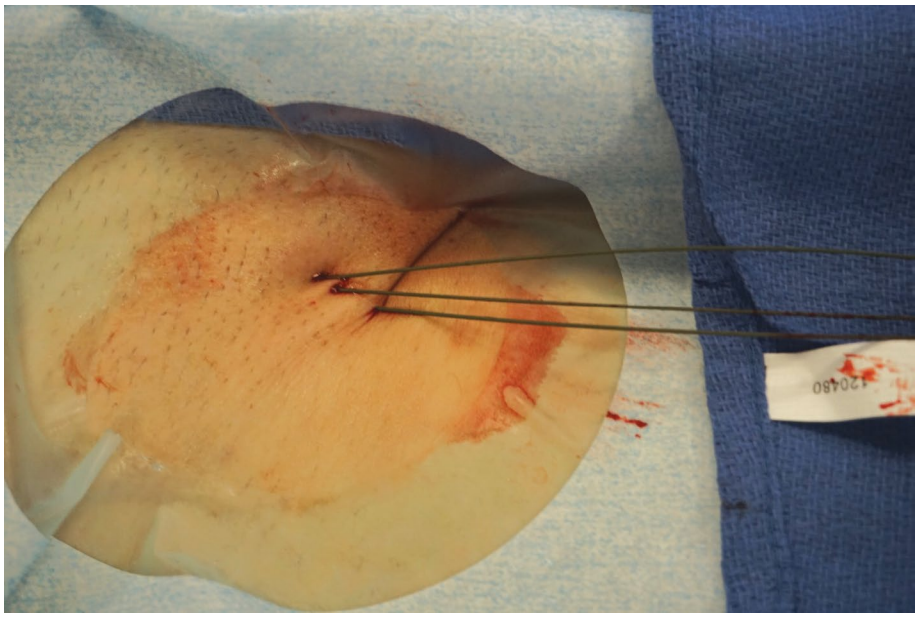

Figure 3: Wire position after gaining access.

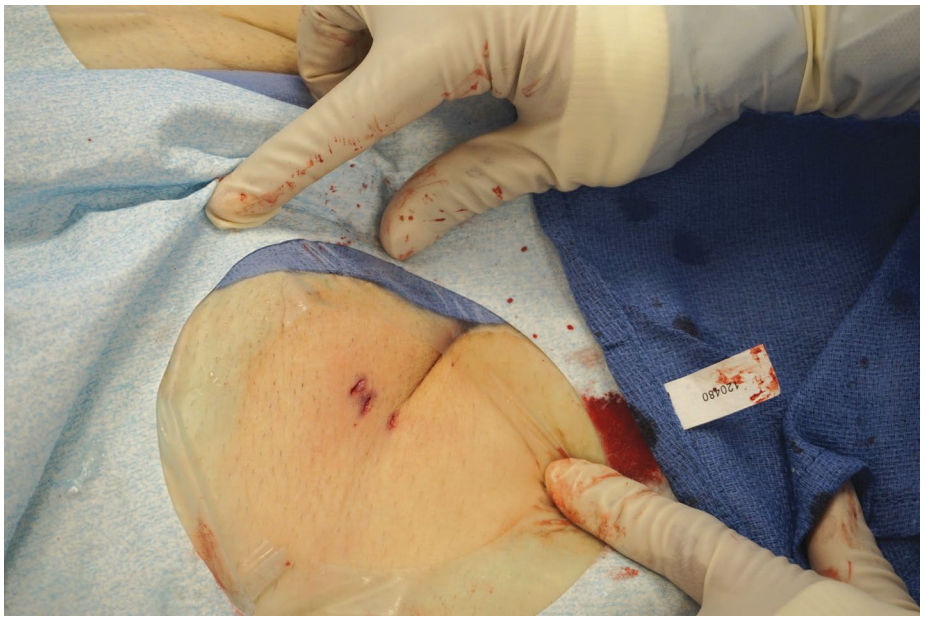

Figure 4: Immediately after VCD deployment (Perclose ProGlide Suture-Mediated Closure System, Abbott Vascular).

Disclosure: Dr. Verma has no conflicts of interest to report regarding the content herein.

References

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IMPORTAN SAFETY INFORMATION

Rx ONLY Perclose ProGlide™ Suture-Mediated Closure (SMC) System

INDICATIONS

The Perclose ProGlide™ Suture-Mediated Closure System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide™ SMC System is indicated for closing the common femoral vein in single or multiple access sites per limb.

The Perclose ProGlide™ SMC System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths. For arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this medical device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and / or interventional catheterization procedures and who has been trained by an authorized representative of Abbott.

Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

During closure of access sites using a procedural sheath greater than 8F, it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to repair the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device.

WARNINGS

Do not use the Perclose ProGlide™ SMC System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Perclose ProGlide™ SMC System is intended for single use only.

Do not use the Perclose ProGlide™ SMC System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site. **Note**: This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral vessel.

Do not use the Perclose ProGlide™ SMC System in arterial or venous access if the puncture is through the posterior wall or if there are multiple punctures in the same access site, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, or the bifurcation of these vessels, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site. **Note**: This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the vessel.

PRECAUTIONS

1. Prior to use, inspect the Perclose ProGlide™ SMC System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
2. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose ProGlide™ SMC System. Employ appropriate groin management, as per hospital protocol, post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the vessel in arterial and venous access.
4. Do not deploy the Perclose ProGlide™ Device at an elevated angle against resistance as this may cause a cuff miss or device breakage.
5. There are no reaccess restrictions if previous arteriotomy / venotomy repairs were achieved with Abbott Medical SMC or SMCR systems.
6. If significant blood flow is present around the Perclose ProGlide™ Device, do not deploy needles. Remove the device over a 0.038" (0.97 mm) (or smaller) guide wire and insert an appropriately sized sheath.
7. Prior to depressing the plunger to advance the needles, stabilize the device by the body to ensure the foot is apposed to the vessel wall and the device does not twist during deployment. Twisting (torquing) the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly depress the plunger. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
8. Do not apply excessive force to the lever when opening the foot and returning the foot to its original position down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.
9. **Do not advance or withdraw the Perclose ProGlide™ Device against resistance until the cause of that resistance has been determined. Excessive force used to advance or torque the Perclose ProGlide™ Device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.**
10. If excessive resistance in advancing the Perclose ProGlide™ Device is encountered, withdraw the device over a 0.038" (0.97 mm) (or smaller) guide wire and reinsert the introducer sheath or use manual compression.
11. Remove the Perclose ProGlide™ sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. Care should be taken to avoid damage to the suture from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.
13. For catheterization procedures using a 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC System to obtain hemostasis.
14. For catheterization procedures using a procedural sheath > 8F, use manual compression, compression assisted devices, surgical repair, and / or other appropriate treatment methods in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC System to obtain hemostasis.
15. For catheterization procedures using a procedural sheath > 8F, where the operating physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary surgical intervention.
16. If the Perclose ProGlide™ Device is used to close and repair multiple access sites in the same vessel, space the access sites apart adequately to minimize sheath-device interference.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use of vessel closure devices may include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to device components
- Vascular access complications which may require transfusion or vessel repair, including:
  - o Anemia
  - o Aneurysm
  - o Arteriovenous fistula
  - o Bleeding / hemorrhage / re-bleeding
  - o Bruising / hematoma
  - o Embolism
  - o Inflammation
  - o Intimal tear / dissection
  - o Perforation
  - o Pseudoaneurysm
  - o Retroperitoneal hematoma / bleeding
  - o Scar formation
  - o Wound dehiscence
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
  - o Atrial arrhythmias
  - o Ventricular arrhythmias
- Femoral artery / venous complications which may require additional intervention, including:
  - o Arterial / venous stenosis
  - o Arterial / venous occlusion
  - o Arteriovenous fistula
  - o Intimal tear / dissection
  - o Ischemia distal to closure site
  - o Nerve injury
  - o Numbness
  - o Thrombus formation
  - o Vascular injury
- Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post-procedure pulmonary embolism)
- Infection – local or systemic
- Pain
- Hemodynamic instability:
  - o Hypotension / hypertension
  - o Vasovagal episode
- Death
- Device complications
- Device failure
- Device malfunction

Rx ONLY FemoStop™ Gold Femoral Compression System

INDICATION FOR USE

The FemoStop™ Femoral Compression System is indicated for use in the compression of the femoral artery or vein after vessel cannulation and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

CONTRAINDICATIONS

- Severe peripheral vascular disease due to the risk of arterial thrombosis.
- Critical limb ischemia.
- Overlying skin necrosis and/or infection.
- Arterial injuries above or near the inguinal ligament.
- The inability to adequately compress due to e.g. coexisting very large hematomas, excessive pain or discomfort (despite anesthetics/ analgesics).
- Patients not suitable for compression of their femoral artery due to leg edema, femoral nerve compression, or arterial obstruction.
- Femoral artery graft or vein graft due to the risk of damage.
- Ultrasound-guided compression repair of infected femoral pseudoaneurysms.

WARNINGS

- For one time use only. Do not reuse or resterilize. Do not use if the original sterile package is not intact. Inspect the system carefully prior to use to verify that all parts are present and undamaged.
- Reuse after cleaning attempts, resterilization and repackaging may result in patient/user infections, product deterioration leading to, e.g. reduced concentration of dome pressure, causing bleeding. Do not disassemble or attempt to repair the system.
- Adequate compression may not be obtained in markedly obese patients.
- Avoid releasing pressure suddenly to reduce any risk of flushing thrombotic material into the artery. Release of thrombotic material may result in embolization which could lead to patient injury.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may occur. A brief interruption at least every three hours of pressure is recommended during long compression periods. Inappropriately long compression and/or immobilization may increase the risk for thrombosis or embolization which could lead to patient injury or death.
- If arterial/venous hemostasis is not achieved, significant bleeding may occur which could result in patient injury or death.
- While removing the sheath, ensure that the pressure applied is kept low, to avoid damage to the vessel or a "milking" effect. Allowance for slight bleeding at the site is preferred to preclude introduction of thrombus to the vessel.
- To prevent limb ischemia, do not leave artery completely blocked for more than 3 minutes. Check pedal pulse periodically to confirm whether or not flow remains in the vessels.
- To minimize the risk for arterial/venous fistula formation, venous hemostasis should be achieved prior to removal of the arterial sheath.
- Do not apply pressure to a femoral artery stent due to risk of damage.

PRECAUTIONS

- The FemoStop™ Femoral Compression System should only be used for compression of the femoral artery or vein after vessel cannulation by or on the order of physicians trained in femoral artery or vein compression procedures.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- When removing the sheath for an Intra-Aortic Balloon Pump (IABP), the Instruction for Use for the IABP should be followed as appropriate.
- For successful compression, the system must be snug and secure around the patient's hips before pressure is applied. Do not over-tighten the belt.
- For successful compression, the system must be correctly positioned throughout the procedure so that pressure is applied to the point intended.
- On very obese patients, it may be necessary to tighten the belt slightly more to enhance downward compression.
- When using the system on obese patients, fatty tissue may be displaced giving a false impression of a developing hematoma.
- Placement of the system may not be suitable on large patients, or patients with very wide hips as the belt may be too short. An abdominal strap/tape may be used to pull excessive adipose tissue away from dome.
- The target inflation pressure should be 10-20mmHg above the systolic pressure, or higher if necessary to control the bleeding. Exceeding pressures of 200mmHg may indicate the need to tighten the belt or reposition the dome.
- Careful monitoring of the dome pressure during the initial period of use is recommended, as the elastic material of the dome may stretch slightly during the first few minutes. You may notice a slight drop in pressure on the manometer. If this occurs, reinflate to initial pressure.
- Ensure that the control knob on the pump is closed when increasing the pressure and open when decreasing the pressure.
- Ensure that the pinch clamp is open when increasing or decreasing the pressure.
- Use of the FemoStop™ Femoral Compression System is not intended to replace careful monitoring of the patient's puncture site. The patient should not be left completely unattended during the time of compression.
- The compression system is for single use only.
- Avoid exposing the pump to any liquid.
- After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- The temperature range on the label represents the temperature for long-term storage.

IMPORTANT SAFETY INFORMATION (CON'T.)

ADVERSE EVENTS

Possible adverse effects that may result from the use of this device include but are not limited to:

- tissue necrosis
- blistering of the skin/skin abrasion
- compression injuries to nerves with subsequent sensory and motor deficits
- femoral artery and/or vein thrombosis
- embolization
- bleeding or hematoma
- arterio-venous fistula or pseudoaneurysm
- acute distension or rupture of a pseudoaneurysm during compression repair

Additional warnings and precautions for ultrasound-guided compression repair of a pseudoaneurysm in the femoral artery

WARNINGS

- To prevent limb ischemia, do not leave artery completely blocked for more than 3 minutes.
- Use color Doppler to periodically confirm whether or not flow remains in the vessels.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may occur.
- During long compression periods, pressure should be briefly interrupted at least every three hours. Use manual compression during this break to limit new flow into the pseudoaneurym.
- Inappropriately long compression and/or immobilization may increase the risk for thrombosis or embolization which could lead to patient injury or death.

PRECAUTIONS

- The FemoStop™ Femoral Compression System should only be used for ultrasound-guided compression repair of a pseudo-aneurysm in the femoral artery, by physicians trained in the treatment of pseudoaneurysms.
- Remove any residual ultrasound gel from the skin overlying the point to be compressed as it may cause the system to slip out of position during the application of pressure.
- Exceeding pressures of 200mmHg may indicate the need to tightly secure the belt or reposition the arch.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *vascular.eifu.abbott* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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