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## **Guidelines for Best Practices for Safe Use of Pneumatic Tourniquets**

#### Introduction

The following Guidelines for Best Practice were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the Guidelines to support healthcare delivery organization's (HDO) reinforce best practices in the use of pneumatic tourniquets as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting. The purpose of the Guidelines is to provide information OR supervisors, risk management, and surgical team members can use in the development and implementation of policies and procedures for the safe use of pneumatic tourniquets in the surgery department. The Guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish policies and procedures for the surgery department regarding *pneumatic tourniquet* practices per HDO protocols.

### Rationale

Pneumatic tourniquets are utilized during extremity surgery to maintain a bloodless field and prevent an anesthetic drug from exiting an extremity during *intravenous regional anesthesia* (IVRA), e.g. *Bier block*. A *tourniquet* applies pressure to the blood vessels to occlude the blood supply to the operative limb.

Even though the pneumatic tourniquet has been placed in the lowest risk category for medical devices by the Food and Drug Administration, Class 1 General Controls, the pneumatic tourniquet can cause nerve, vessel and tissues injuries to the patient, temporary or permanent, due to incorrect cuff placement, incorrect size of tourniquet, excessive tourniquet pressure, prolonged inflation and improper protection of the skin underlying the tourniquet.<sup>1,2</sup> The most commonly reported complication associated with the use of pneumatic tourniquets is pain.<sup>3</sup> As far back as 1985, the Arthroscopy Association of North America completed a national survey in which 930 complications were reported in 118,590 arthroscopic procedures. Sixty-three of the complications were neurological injuries, and of those, fifty of the complications were due to the use of a tourniquet.<sup>4</sup> In 2006, Odinsson et al. published the results of its survey of 265 surgeons. The authors stated that eighteen complications were reported that included three cases of blistering and skin necrosis; two cases of permanent lower-limb nerve complications; thirteen nerve complications that resolved within six months of surgery; six cases involving paresis; six cases involving sensory disturbance; and one case involving complete sensory and motor palsy in the arm.<sup>5</sup> The Pennsylvania Patient Safety Authority (PSA) collected data from December 2004 though December 2009 and stated there were 140 reported patient

incidences due to pneumatic tourniquet use.<sup>6</sup> The data showed that 41% of the incidences involved bruising and swelling of the tissues and 19% involved blistering or tears of the skin.<sup>6</sup> There are many other reported complications; systemic complications are further addressed in Guideline II, while injuries such as to the skin and nerves are addressed in conjunction with patient safety aspects in Guideline III:

- Nerve injuries;<sup>4,5,7</sup>
- Pulmonary embolism;
- Injuries to the blood vessels;
- Injuries to the skin and underlying tissues;
- Temperature changes, particularly pediatric patients;<sup>3,8</sup>
- Postoperative swelling of tissues and compartment syndrome;<sup>9,10</sup>
- Cardiovascular, hematological and respiratory systemic effects when the pneumatic cuff is deflated and metabolic wastes that built up due to ischemia are released into the circulatory system.<sup>10,11</sup>

The Guidelines, as stated in the introduction, are meant to provide general information and recommendations that focus on patient safety to avoid complications. The duties of the CST are those described in the role of assistant circulator; henceforth, it will only be indicated if a duty is in the first scrub role. Additionally, there are tasks that are exclusively the responsibility of the surgeon and/or anesthesia provider to perform that will be indicated in the guidelines.

Due to the degree of information regarding the various types of pneumatic tourniquet systems that are available on the market, surgery personnel are strongly recommended to be familiar with the manufacturer's instructions for use (IFU) for each system the surgery department uses. Only pneumatic tourniquets are discussed in this document; it is beyond the scope of this document to include discussion of the use of non-pneumatic tourniquets, e.g., Esmarch bandage, Penrose drain, rubber bands.

The components of the pneumatic tourniquet consist of the:

- Connective tubing: Connects the cuff to the pressure device
- Inflatable cuff: Consists of a rubber bladder that is within a plastic or fabric covering. Cuffs may be a single cuff that contains a single chamber for the air or a double cuff that contains two chambers.
- Pressure device: Consists of the air compressor, buttons for setting the pressure, digital display of the pressure setting and timer. The pressure device is run by electricity; therefore, the unit is plugged into a wall outlet. Some units contain a battery that can run the device for a short period of time during power outages.

### **Evidence-based Research and Key Terms**

The research of articles, letters, nonrandomized trials, and randomized prospective studies is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles.

The key terms used for the research of the Guidelines include: Bier block; compartment syndrome; exsanguination; intravenous regional anesthesia; knee arthroscopy; limb occlusion pressure; pneumatic tourniquet; total knee arthroplasty or replacement; tourniquet. Key terms used in the Guidelines are italicized and included in the glossary.

#### **Guideline I**

The CST should know if the patient plan for surgery involves the use of a pneumatic tourniquet.

- 1. The surgeon and/or anesthesia provider make the decision if a pneumatic tourniquet (herein referred to as tourniquet) is or is not required based upon the results of the patient's history and physical, contraindications such as existing disease condition(s) and type and length of surgical procedure.
  - A. CSTs should not assume that a tourniquet will be used for surgical procedures on the extremities. Studies have provided evidence that the use of a tourniquet in all instances of extremity surgery may be unnecessary and the CST should confirm with the surgeon and/or anesthesia provider if a tourniquet will be used.
    - Johnson et al. (2000) conducted a prospective randomized trial in the study of knee arthroscopies and tourniquet use in 109 patients. Patients were assigned to one of two groups; one group the tourniquet was inflated and the other not inflated. The authors reported there was no significant difference between the two groups regarding analgesic requirements, complications, duration of procedure, operative view and pain scores. The authors recommended that the routine use of a tourniquet for *knee arthroscopy* should be discontinued.<sup>12</sup>
    - 2) Kirkley et al. (2000) conducted a prospective, double-blind randomized clinical trial involving 120 patients that underwent a *knee arthroscopy*. Sixty-one patients were assigned to the notourniquet inflation group and fifty-nine to the tourniquet inflation group. Patients recorded their average pain on a visual analog scale and narcotic use for five days postoperatively. The authors reported that visualization was much better in the inflated tourniquet group, but the average operative time did not differ between the two groups. However, it was reported that the notourniquet inflation group had a decreased level of postoperative pain. An issue associated with the study is that the surgeons could view if the tourniquet cuff was inflated or not inflated, thus causing a bias. The authors concluded that the use of a tourniquet during knee arthroscopy did not significantly affect overall patient quality of life or functional outcome postoperatively.<sup>13</sup>
    - 3) Tetro and Rudan blindly randomized sixty-three patients that were scheduled for *total knee arthroplasty* into 33 in a tourniquet group and 30 non-tourniquet. The complication rates, hospital stay, operating time, perioperative blood loss and transfusion needs were recorded. The authors reported that the difference in the total measured blood loss, intraoperative blood loss and Hemovac drainage blood loss between the two groups were not significantly different.<sup>14</sup> The authors concluded that the effectiveness of a pneumatic tourniquet during total knee arthroplasty is uncertain.<sup>14</sup>

- 4) Researchers conducted a randomized controlled trial involving 100 patients undergoing a total knee arthroplasty. The study was conducted to determine if epinephrine-augmented hypotensive epidural anesthesia could be used in place of a tourniquet without effecting hemoglobin values. Group A consisted of forty-nine patients who received epinephrine-augmented hypotensive epidural anesthesia and Group B that received normotensive epidural anesthesia with a tourniquet. The researchers evaluated hemoglobin values preoperatively, intraoperatively and six hours postoperatively, as well as postoperative days one through three, five and six. The researchers reported epinephrine-augmented hypotensive epidural anesthesia is an effective method to avoid tourniquet use during total knee arthroplasty without negative effects on perioperative hemoglobin values.<sup>15</sup>
- 5) Smith and Hing completed a meta-analysis and systematic review of the databases Medline, CINAHL, AMED and EMBASE as well as a personal search of orthopedic journals; the articles were assessed using the Cochrane Bone, Joint and Muscle Trauma Group. The authors compared the outcomes of tourniquet-assisted to non-tourniquet assisted total knee arthroplasty. Fifteen studies were identified involving 1,040 procedures in 991 patients. The researchers reported there was no significant difference between the two groups for total blood loss or transfusion rate. However, they identified there were more complications in the patients with tourniquet.<sup>16</sup> The researchers concluded that there is no advantage to using a tourniquet in total knee arthroplasty to reduce transfusion requirements.<sup>16</sup>
- 6) A prospective, double-blind randomized clinical trial was conducted to evaluate whether tourniquet use effects the duration of surgery, recovery of movement and joint volume in patients who underwent a knee arthroscopy with partial meniscectomy using an arthropump with pressure sensor. 103 patients were divided into Group 1 consisting of fifty-one patients without an inflated tourniquet and Group 2 consisting of fifty-two patients with inflated tourniquet. The researchers reported there was no statistically significant differences among any of the variables and therefore, concluded that there are no reasons for justifying or discrediting tourniquet use as long as the arthropump with sensor is used.<sup>17</sup>
- 7) A meta-analysis was completed to examine whether using a tourniquet during total knee arthroplasty was effective but did not increase the risk of complications. Eight randomized trials and three high-quality prospective studies involving 634 total knee arthroplasties with and without the use of a tourniquet were included in the meta-analysis. The researchers reported that the results of the analysis revealed that using a tourniquet provided

good visualization of the surgical site, but it did not reduce the actual blood loss. They further reported it decreased operation time only when it was released after wound closure and dressing. Lastly, the tourniquet might be associated with an increase in thromboembolic events and wound complications. The researchers recommend that surgeons should carefully consider the effectiveness and safety of using a tourniquet during total knee arthroplasty and inflating the tourniquet only during cementing the prostheses in place or for a limited time might be options to consider.<sup>18</sup>

8) A randomized study was conducted to evaluate the effects of tourniquet use during total knee arthroplasty on functional and clinical outcomes and knee range of motion (ROM). Seventy patients were divided in half – thirty-five with tourniquet, thirtyfive without. Patients in the non-tourniquet group had a better outcome in all knee injury and osteoarthritis outcome scores (KOOS) and better early knee ROM from time of surgery to postoperative week eight. However, no differences were recorded at the six- and twelve-month patient follow-ups. Postoperative pain and analgesic use were less in the non-tourniquet group; intraoperative blood loss was greater but did not require postoperative transfusions. Surgical time and visibility of the surgical site were similar. The researchers concluded that performing a total knee arthroplasty without a tourniquet results in faster recovery with improved knee ROM and was also associated with reduced pain and analgesic use.<sup>19</sup>

# **Guideline II**

CSTs should be well-informed of the systemic complications related to the use of a pneumatic tourniquet to be an effective team member in supporting the care of the patient.

- 1. Deep vein thrombosis (DVT), pulmonary embolism and peripheral artery disease (PAD) are concerns of the surgeon and anesthesia provider during tourniquet use. The time periods of when the limb is exsanguinated and after cuff deflation present the potential for hemodynamic instability in the patient. An important correlation was reported between the occurrence of emboli and the length of tourniquet inflation.<sup>20</sup> The surgical team should be aware that DVT leading to pulmonary embolism can be a consequence of the patient experiencing intraoperative hemodynamic fluctuations and be prepared to assist the surgeon and anesthesia provider with immediate treatment.<sup>9,21,22</sup>
  - A. Aglietti et al. (2000) conducted a study of twenty patients who underwent total knee arthroplasty (TKA); they were separated into two groups of ten with and without a tourniquet. Blood samples were collected during the perioperative period that indicated a systemic increase in prothrombin, thrombin and antithrombin.<sup>23</sup> The authors concluded that the use of a

tourniquet can enhance fibrinolysis and prevent DVT in patients undergoing a TKA.<sup>23</sup>

B. Arterial complications after tourniquet use are rare, but they could damage the intravascular endothelium.<sup>9</sup> Complications after TKA could lead to vascular reconstructive surgery or extremity amputation, especially if the patient suffers from PAD or underwent previous peripheral arterial reconstruction on the extremity in which the TKA was performed.<sup>24</sup>

The CST should know when the tourniquet may be used when the patient suffers from arterial calcifications such as what occurs with diabetes mellitus. Risks could include failure to achieve a blood-less surgical site causing difficulties for the surgeon to view the site, systemic toxicity from anesthetic agents that were not blocked from escaping; and an increase in the risks of tourniquet-related complications because a higher cuff pressure is required to achieve arterial occlusion.<sup>25</sup> Jeyaseelan et al. (2007) reported a case of a patient with calcification of the femoral artery wall and the tourniquet failed.<sup>26</sup> Excessive hemorrhaging occurred at the surgical site due to the failure to achieve arterial occlusion, but venous occlusion was achieved.<sup>26</sup>

- C. Berman et al. (1998) studied the effect of tourniquet release on hemodynamic stability by imaging the right atrium and left ventricle of fifty-five patients during fifty-nine total knee arthroplasties. A tourniquet was used inflated to 350 mm Hg. The authors observed echogenic material travelling through the right atrium, left ventricle and pulmonary artery in all patients after the tourniquet was deflated, lasting three to fifteen minutes.<sup>21</sup> Blood aspirated from five of the ten femoral vein catheters displayed fresh venous thrombus, but the histological evaluation of the aspirates did not show evidence of particles of polymethyl methacrylate.<sup>21</sup> The authors concluded that the time period after deflation of the cuff is the critical period for hemodynamic instability and pulmonary embolism as a potential cause.<sup>21</sup>
- D. Hirota et al. (2001) conducted a study of thirty patients undergoing arthroscopic knee surgery and compared the use of a tourniquet to pulmonary emboli using transesophageal echocardiography (TEE) to obtain the results. The authors reported that TEE detected emboli in all patients and the peak level of emboli occurred forty to fifty seconds after the cuff was deflated, but no patients experienced symptoms of pulmonary embolism.<sup>27</sup> The authors concluded that acute pulmonary embolism can occur within one minute of cuff deflation and the peak amount of emboli is related to the time length of cuff inflation.<sup>27</sup>
- 2. It is the decision of the surgeon and/or anesthesia provider to perform a procedure with the use of a tourniquet in the presence of a patient's hematologic disorder.<sup>28</sup> In sickle cell disease, sickling can be triggered by acidosis, circulatory stasis and hypoxemia which occur during tourniquet use.<sup>11</sup> Al-Ghamdi (2004) reported the use of a pneumatic tourniquet performing a bilateral total knee replacement on a patient with sickle cell disease. He reported the patient was stable throughout the procedure and the results of six arterial blood samples taken during tourniquet

inflation and deflation showed no significant increase in sickled cells compared to preoperative samples.<sup>29</sup> He concluded that patients with sickle cell disease should not be denied an operative procedure that requires the use of a tourniquet if the procedure is necessary and the steps are taken to minimize sickling. Other evidence suggests that with proper precautions, tourniquets may be able to be used with no significant damaging effects to the sickle cell patient. A complication rate of 12.5% was reported in four studies included in a review article that involved ninety-six patients.<sup>30</sup>

- 3. Constriction and subsequent ischemia of extremities causes metabolic changes that include build-up of lactic acid and increased levels of PaCO<sub>2</sub> and potassium, and decreased levels of PaO<sub>2</sub> and pH.<sup>10,11</sup> Upon cuff deflation the anaerobic metabolites are immediately released into the patient's systemic circulation. The metabolites cause a syndrome called "myonephropathic metabolic syndrome" that can cause hyperkalemia, hypotension, metabolic acidosis, myoglobinuria, myoglobulinemia and possibly renal failure.<sup>11,25,31</sup> The extent of the syndrome depends on the age and health status of the patient, duration of tourniquet time and size of the extremity.<sup>10</sup> Additionally, the metabolic changes are increased when bilateral tourniquets are used.<sup>11</sup> Typically the metabolic changes are reversed within thirty minutes after cuff deflation.<sup>11</sup>
- 4. The cardiovascular system is affected by the use of a tourniquet starting with *exsanguination* through deflation. Healthy patients are minimally affected by the hemodynamic changes, but patients with deficient cardiac function can be adversely affected. Exsanguination and cuff inflation causes an increase in the central venous pressure (CVP).<sup>9,32,33</sup> Diastolic and systolic pressures and heart rate increase after 30 60 minutes of cuff inflation due to ischemia and tourniquet pain and continue until the cuff is deflated.<sup>11</sup>

Monitoring the patient is critical during cuff deflation because it causes a rapid decrease in CVP and arterial pressures.<sup>10,11</sup> The short period of hypotension after cuff deflation can cause myocardial depression and possibly cardiac arrest.<sup>33-36</sup> These hemodynamic changes are due to both an influx of blood volume back into the extremity and the rapid entry of metabolites that built-up in the extremity into the systemic circulation.

5. Changes to the respiratory system rarely occur and if it occurs it is usually during cuff deflation.<sup>11</sup> The end-tidal carbon dioxide (EtCO<sub>2</sub>) increases due to the rapid entry of hypercapnic venous blood and metabolites into the patient's systemic circulation.<sup>9,10,33</sup> Increases in the EtCO<sub>2</sub> are also related to the length of ischemia, use of the tourniquet on lower extremities and males are affected more than females due to males usually having a greater muscle bulk.<sup>11</sup> The EtCO<sub>2</sub> usually returns to normal baseline readings within 10 - 13 minutes after cuff deflation in spontaneously breathing patients but may take longer in mechanically ventilated patients.<sup>33-36</sup>

Cerebral circulation is affected by the increased EtCO<sub>2</sub>; after cuff deflation the cerebral blood flow is increased for approximately two minutes and returns to normal in about ten minutes. However, patients who have a compromised cerebral circulation may be at an increased risk for complications. The anesthesia provider will attend to maintaining normocapnia levels in the patient to prevent the increase in cerebral blood flow during deflation.<sup>33,37,38</sup>

- 6. Body temperature is affected by the use of a tourniquet starting with exsanguination through deflation and cooling in the occluded limb due to ischema.<sup>10</sup> The core body temperature increases after tourniquet application due to the decrease in surface area for heat to escape causing less heat to transfer from the core to the periphery of the body. Upon cuff deflation, the core body temperature decreases as the body heat is allowed to escape to the periphery and hypothermic blood from the extremity enters the systemic circulation. The anesthesia provider maintains the core body normothermia during surgery to control the decrease in temperature.<sup>39,40</sup>
- 7. As previously stated, tourniquet pain is the most commonly reported tourniquet complication; pain is reported to develop in up to 66% of patients approximately 30 60 minutes after cuff inflation.<sup>10</sup> Patients report a dull, aching sensation at the site of the tourniquet.<sup>11,41,42</sup> The pain occurs more often with the use of general anesthesia as well as occurs most often during lower extremity surgery.<sup>11</sup> The pathophysiology is not completely understood, but it is thought to be caused by a combination of factors including a cutaneous neural mechanism as well as release of prostaglandins.<sup>43</sup> Many techniques as well as IV drugs including intra-articular injection of local anesthetics have been studied to attempt to decrease the incidence and/or severity of pain, but the only real method that works is cuff deflation.<sup>44,45</sup>
- 8. Due to cuff inflation the extremity will obviously be insulated from receiving other systemic drugs and therefore, timing the administration of parenteral prophylactic antibiotics is a critical consideration of the surgeon and anesthesia provider to prevent postoperative infection. It's obviously important that the antibiotic be completely infused and absorbed by the systemic circulation to be effective.<sup>9,46</sup> Clinical studies have suggested that prophylactic antibiotics be administered 5 20 minutes prior to cuff inflation to allow for thorough tissue penetration and entry into the systemic circulation.<sup>9,46-48</sup> However, it has also been reported that antibiotic administration ten minutes prior to cuff deflation may be just as effective.<sup>49</sup>

### **Guideline III**

The CST should know the surgeon's and anesthesia provider's overall patient plan for the use of a tourniquet including where the tourniquet will be positioned, size and type of tourniquet, pressure setting, assessment of the patient's skin condition and contraindications for use of a tourniquet. Additionally, the CST should contribute toward patient safety by inspecting and testing the tourniquet prior to patient use.

- 1. The CST should know how to set-up the tourniquet system for testing and patient use. The manufacturer's IFU should always be followed for testing and patient use, and the IFUs should be available in the operating room (OR) while the tourniquet system is being used on a patient.
  - A. Some tourniquet systems can be mounted on IV poles while others are table top units or mounted on portable stands. The CST should know how to place the tourniquet system on the IV pole or portable stand.

- 2. Non-disposable tourniquets should be inspected and tested prior to patient use.<sup>10,50</sup> Tourniquet systems may have automatic cuff testing capability imbedded in the system that allows quick, but thorough testing of the cuff prior to use and after disinfecting.<sup>51</sup> Additionally, the tourniquet system may have an automatic cuff leak detection embedded in the system that can detect leaks in the cuff, connectors and tubing, thus assisting the CST during testing as well as alerting the surgical team during a procedure.<sup>51</sup> If any of the following damages exist the cuff is considered no longer usable and should be disposed of in the correct waste container.
  - A. The cuff and tubing should be checked to confirm they are clean and no cracks, holes or rips are present.<sup>50,52</sup> Additionally, the stiff structure inside the cuff should be palpated through the outer cuff material to determine if permanent kinks or ridges have formed, particularly on the inner surface that will directly contact the patient.<sup>53</sup>
  - B. All tourniquet connectors should have locking connectors that secure the cuff tubing to prevent inadvertent detachment and should be inspected to confirm they are not loose.<sup>6.50</sup> The connectors should be inspected to confirm they are not bent, broken or worn, and the black O-ring on each connector is not cracked, damaged or missing.<sup>53</sup> Units with Luer-lock connectors must be removed from service to prevent accidental connections to the patient's IV tubing and infusion pump administration sets to avoid the patient from acquiring an air embolism.<sup>6.54</sup>
  - C. If there are tie ribbons they should be inspected for fraying or tears.<sup>53</sup> Tie ribbons are used to stabilize the position of the cuff by providing a secure cuff application and prevent the cuff from moving during the surgical procedure.

Cuffs are available with releasable application handles that should be inspected for tears, fraying and proper operation. Releasable application handles provide an improved cuff application, faster cuff removal and are an improvement over tie ribbons in maintaining the position of the cuff during the surgical procedure.<sup>55</sup>

- D. The Velcro material (hook and loop) should be inspected for tears or if the stitching is broken or frayed.<sup>53</sup> Additionally, the Velcro should be inspected to ensure that fibers from the cleaning cloth that cannot be removed are not imbedded in more than 25% of the contact closure that could prevent adequate closure of the cuff.<sup>53</sup>
- E. If the system uses a battery for power, the battery should be checked to confirm it has adequate power for the duration of the procedure; a self-test should be performed.<sup>6</sup> Additionally, the tourniquet system should have a back-up battery that ensures normal function in the event the health care facility experiences a power-supply outage.<sup>25</sup> If a tank is used to provide pressure to inflate the cuff the gas level should be checked prior to the patient entering the OR; additionally, the hose that attaches the cuff to the tank should be inspected to make sure the connectors are not damaged and the hose is long enough.<sup>53,54</sup>

- F. The tourniquet should be inflated and deflated to test the system and check for leaks.<sup>50</sup> The cuff should be connected to the tourniquet system, wrapped upon itself and inflated and inspected for leaks. There are tourniquet systems available on the market that include the technology to automatically perform a system check to ensure the components are working properly and will alert the user of any possible hazards or damage.<sup>53</sup>
- G. Inspect the electrical cord for fraying or damage. If damaged, electrical tape must not be used to repair the cord and the tourniquet unit should be replaced and sent to the HDO's biomedical engineering department for repair.<sup>56,57</sup>
- H. Tubing should be kept off the floor to protect from damage and prevent surgical personnel from becoming entangled and falling.<sup>6,54</sup> The tubing should also be checked to ensure it is not kinked or occluded.<sup>52</sup> Dual-line cuffs are available that facilitate the detection of kinks or occlusions ion the line.<sup>25</sup>
- Disposable tourniquet cuffs are a sterile item that are indicated for use on a onetime basis and disposed of after use in the contaminated waste. Disposable cuffs are useful when the cuff needs to be positioned near the operative site or for contaminated surgical procedures.<sup>58</sup>
  - A. Reprocessing a disposable cuff could cause safety hazards for the surgical patient since the manufacturer has not designed the cuff for reprocessing and reuse.
    - Cuff materials may deteriorate or be damaged due to exposure to the chemical or physical agents during disinfection and resterilization.<sup>53</sup> Exposure of the thermoplastic materials to higher temperatures during re-sterilization can soften materials causing components such as the tubing, connectors and ports to be damaged. A damaged connector could cause the cuff to separate from the tourniquet system, resulting in unanticipated deflation of the cuff, loss of extremity occlusion and loss of the blood-less surgical site.
    - 2) During disinfection and re-sterilization liquids may enter and block the portal openings and inflatable portion of the cuff. If water remains within the cuff it can react with ethylene oxide during resterilization forming the semi-solid substance ethylene glycol which can block the portal openings and inflatable portion of the cuff, as well as be dangerous to the patient and surgical personnel since ethylene glycol is toxic. Blockage of a port(s) can affect the pressure regulation within the cuff during patient use.<sup>53</sup>
- 4. Tourniquet systems use air or nitrogen to inflate the cuff bladder. The manufacturer's IFU should be followed to select the correct gas to be used with the tourniquet system. Oxygen or nitrous oxide must never be used to inflate the cuff bladder since this increases the risk of fire in the OR; if a tourniquet system uses either gas it should be removed from service.<sup>6,50,59</sup>

- A. In 1982, ECRI reported an adverse event whereas oxygen that leaked from a tourniquet connector was trapped under the surgical drape; the drape became ignited by a disconnected fiberoptic cable and the patient suffered severe burns to the legs when a flash fire occurred.<sup>60</sup>
- 5. The patient's general health and skin condition should be assessed prior to tourniquet placement. Accurate patient assessment prior to surgery assists in making decisions that individualize the use of the tourniquet, e.g. size of tourniquet; contour or straight tourniquet required; and identifying patient complications that could occur during inflation and deflation of the cuff.
  - A. The integrity and quality of the patient's skin should be assessed prior to tourniquet placement and documented in the OR record. Skin injuries are uncommon but can occur due to excessive tourniquet time and poorly positioned cuffs that result in cutaneous abrasions, blisters and possibly pressure necrosis.<sup>11</sup> Patients at highest risk for skin injuries are elderly, obese, and pediatric patients as well as those with peripheral vascular disease.<sup>11</sup>
  - B. A baseline measure of the peripheral pulses should be recorded to evaluate the risk of using a tourniquet.<sup>61</sup> Other circulatory indicators to take under consideration include capillary filling time and the presence of varicose veins.<sup>61</sup>
  - C. CSTs should be knowledgeable of the contraindications for tourniquet use. However, it must be emphasized that the final decision of whether or not to use a tourniquet is that of the surgeon.
    - Exsanguination and the use of a tourniquet is usually avoided when the patient has an open fracture or other extremity injuries because it is necessary for the surgeon to be able to assess the devascularized area of the injury if debridement is necessary.<sup>62</sup> Use of the tourniquet could cause the surgeon to underestimate the extent of the zone of the injury.<sup>62</sup> Additionally, the anoxia produced by the tourniquet interferes with the surgeon's ability to assess the viability of the muscle and increase the pre-existing anoxia associated with the injury.<sup>62</sup>

In the instance of a closed fracture, exsanguination may not be able to be accomplished with the use of an Esmarch bandage; use of the bandage could further injure the patient. Elevation of the extremity may be the only route of accomplishing some degree of exsanguination. However, elevation also may not be able to be performed due to the severity of the closed fracture and the possibility of causing further neurovascular damage.

2) Exsanguination of the extremity with an Esmarch bandage prior to inflating the cuff is not recommended in the presence of infection, malignant tumor or thrombin in the extremity.<sup>11</sup> Using the bandage could push the infectious fluid, malignant cells or thrombi into the patient's systemic circulation.<sup>11</sup>

- 3) The patient should also be screened for the following contraindicatons:<sup>10,11,58</sup>
  - Acidosis
  - Skin grafts
  - Diabetes mellitus
  - Reynaud's disease
  - Severe hypertension
  - Severe crushing injuries
  - Medications and supplements
  - Increased intracranial pressure
  - Extremities with dialysis access
  - Previous revascularization of the extremity
  - Post-traumatic lengthy hand reconstruction
- 6. To reduce intra-and post-operative complications, the appropriate size of cuff should be chosen according to the characteristics of the patient, e.g. circumference of limb, shape of limb, preexisting conditions, type of surgical procedure.<sup>11</sup>
  - A. The surgery department should maintain an adequate inventory of cuff sizes; routine sizes are 8, 10, 18, 24, and 34 inches.<sup>6,11</sup>
  - B. The widest cuff possible should be chosen that doesn't interfere with the surgical site.<sup>10</sup> Wide bladders can occlude the blood flow with the use of a lower cuff pressure, thus reducing the risk of injury to the patient.<sup>63</sup>
    - The size of the cuff should be wider than half of the limb's diameter.<sup>11,64</sup> Preoperative assessment of the patient may include the surgeon and/or anesthesia provider using a nonstretch measuring tape to measure the circumference of the patient's extremity in order to choose the proper size of cuff.<sup>53</sup>
    - 2) Estebe et al. (2000) conducted a study comparing tourniquet pain tolerance using a narrow and wide cuff placed on each arm of the 20 volunteers; one cuff was inflated at 100 mm Hg above systolic blood pressure and the other at the lowest effective occlusive pressure. The authors concluded that a wide-cuff is more effective than a narrow cuff in occluding the blood vessels and that it is less painful when the pressure is less than 100 mm Hg and pressure is based on arterial pulse loss.<sup>9</sup>
  - C. Contour cuffs are recommended for conical or tapered extremities such as encountered in muscular and obese patients to reduce the excessive pressure on one edge of the cuff.<sup>2,9,65</sup> Contour cuffs have been proven to occlude the blood flow at lower pressures than straight cuffs and when combined with LOP, can significantly reduce the cuff pressure needed to achieve vessel occlusion in both adult and pediatric patients.<sup>25,66</sup> Additionally, straight cuffs transmit the pressure unevenly to the thicker portion of the extremity rather than uniformly across the cuff width.<sup>65</sup> Therefore, the use of a wide, contoured tourniquet is recommended to achieve the lowest possible LOP.<sup>25</sup>
    - 1) There are two types of contour cuffs: non-variable contour, also referred to as fixed-contour cuff, and variable-contour cuff. Non-

variable contour cuffs are designed to fit one specific limb shape.<sup>67</sup> Variable-fit contour cuffs incorporate fasteners with pivoting securing straps that allow the cuff to adapt to and match the proximal and distal circumference of limbs of different sizes and shapes while also allowing the cuff to be secured by dual independent fasteners for improved safety.<sup>67</sup> This design allows the cuff to fit uniformly onto extremities that have a wide range of shapes and circumference.

- 7. The tourniquet cuff should be applied according to manufacturer's IFU, HDO policies and procedures, and standards that have been established through evidence-based research.
  - A. The cuff should be positioned on the limb at the point of maximum circumference which provides maximum protection for the prevention of nerve and tissue injury.<sup>10,11</sup> For the arm the cuff should be placed in the middle between the shoulder and elbow; upper leg, the cuff should be placed on the proximal third of the thigh. The cuff should not be placed directly over a bony prominence such as the fibular head as this can place undue compression on a nerve(s).<sup>10</sup> Therefore, it is recommended that the edge of the cuff should be at least 2 4 centimeters distal to the fibular head to avoid injury to the common peroneal nerve and two centimeters proximal to the malleoli when the cuff is placed on the gastrocnemius muscle.<sup>9,10</sup>
  - B. Tourniquets are usually positioned on upper arm for upper extremity surgery. However, studies have confirmed that surgeons have ordered the tourniquet to be positioned on the forearm and the literature supports the efficacy and safety of the practice.<sup>68</sup> During IVRA, forearm tourniquets have been shown to require a lower dose of local anesthetic.<sup>69</sup> Odinsson et. al (2006) agreed with the results of studies, however, they reported that surgeons had greater difficulty in performing the surgical procedure when the tourniquet is positioned more distally.<sup>5</sup> Therefore, as previously stated, the CST in the assistant circulator role should confirm with the surgeon and anesthesia provider the location/position of the tourniquet.
  - C. Studies have proven that it is necessary to protect the skin underlying the cuff to prevent blisters and other more serious injuries to the skin and subcutaneous layer.<sup>70</sup> Additionally, studies have given evidence that limb protection sleeves provide the optimal protection of skin that underlies a tourniquet and the greatest protection is provided by using limb protection sleeves that are specifically matched to the limb size and cuff.
    - Olivecrona et al. (2006) conducted a randomized study of 92 patients undergoing a TKA who were divided into three groups – group one the extremity was protected by a two-layer elastic stockinette; group two the extremity was protected by cast padding; group three no protective material was used. The two groups with skin protection had fewer skin injuries and no patient with the stockinette protection experienced blisters, three blisters

occurred in patients with cast padding and seven blisters occurred in the patients with no protection.<sup>70</sup>

2) Matching limb protection sleeves are corresponded to the cuff. The sleeves consist of elastic, low-linting soft material that are sized to match the size range of the matching cuff.<sup>55</sup> Some manufacturers color code their matching limb protection sleeves to ensure the correct sleeve is used with the correct cuff. However, the color coding is specific to each manufacturer, so the sleeves and cuffs from different manufacturers should not be mixed.<sup>55</sup>A sleeve that is not specifically matched to the cuff may not provide enough protection to the underlying skin and subcutaneous tissue, may impede the proper performance of the cuff and could interfere with venous blood flow return when the cuff is deflated.<sup>55</sup>

Tredwell et al. (2006) conducted a quantitative analysis of forty-four trials applying a pediatric cuff on two healthy child volunteers in which a tourniquet was used. The matching limb-protection sleeve that was specific to the pediatric cuff produced significantly fewer and less severe pinches and wrinkles of the skin as compared to other methods of skin protection.<sup>71</sup>

McEwen et al. (2002) conducted a study where fifty-five trials of five different limb protection types were tested on the upper arms and thighs of five adults. The matching sleeves made of two-layers of tubular elastic material matched to specific cuffs produces significantly fewer and less severe pinches and wrinkles of the skin as compared to other types of padding that were tested.<sup>63</sup>

- 3) If a matching limb protection sleeve is not used, a minimum of two layers of wrinkle-free padding should be placed around the extremity as proximal to the surgical skin incision as possible.<sup>9,10</sup> Cotton-cast padding, sheet padding or Webril should not be used due to their shedding loose fibers/lint that can become embedded in the Velcro closures of the tourniquet and reduce the ability to obtain an effective application of the cuff or create the possibility of the cuff becoming loose during the procedure.<sup>6,63</sup>
- D. When the cuff is applied it should be flat and even since the effectiveness of the cuff can be compromised if it becomes bent, crinkled or folded causing insufficient pressure to be applied that can result in the local anesthetic entering the systemic circulation and blood entering the surgical site as well as injuring the underlying skin.<sup>52</sup>

The cuff should overlap at least three inches, but not more than six inches/beyond the Velcro.<sup>6,11,72</sup> If the overlap is more than six inches, this can cause rolling and wrinkling of the soft tissues and increased pressure in the area of the overlap.<sup>11,52</sup> If the overlap is too small the cuff pressure is compromised that can result in unexpected release of the cuff or inadequate compression.<sup>11</sup>

If tie ribbons are used to achieve a secure application, the tie ribbons and the fastener straps should be pulled in opposite directions around the limb and then engage the fasteners. The tie ribbons and fastener straps should not be pulled away from the extremity as this may result in a loose cuff.<sup>73</sup>

When the cuff is correctly positioned, the cuff tubing should be located on the lateral side of the extremity to avoid placing pressure on nerves or the tube kinking.<sup>11,73</sup>

A securely applied cuff should allow the CST to easily slide two fingers under the proximal and distal cuff edges.<sup>73</sup> If only one finger can be slid under the cuff is too tight; if three fingers can be slid under the cuff is too loose.

- E. When applying the cuff to an obese patient, it is recommended that the assistant circulator CST apply distal traction to the skin and subcutaneous tissue of the extremity with the use of the hands to smooth out the skin and tissue while the cast padding and tourniquet cuff are applied.<sup>25</sup>
- F. When applying the cuff to a pediatric patient it is recommended that the most proximal portion of the limb is selected as the cuff location.<sup>71</sup>
- G. After the cuff is applied and the patient skin prep is being performed, the prep solution should not be allowed to pool around or under the cuff to prevent chemical burn to the patient's skin.<sup>6,10,64</sup> A self-adhesive plastic drape should be positioned around the distal edge of the cuff while the skin prep is performed.<sup>74,75</sup>
- H. If a non-sterile cuff is used it should be covered to reduce gross contamination from the surgery site and also prevent a SSI. Typically, the edge of a sterile plastic U-drape is positioned around the distal edge of the cuff and unfolded towards the patient's head to cover the cuff.<sup>63,76</sup>
- 8. When possible, the extremity should be exsanguinated prior to inflating the cuff. The assistant circulator CST may be responsible for elevating the extremity to contribute to exsanguination of blood. An Esmarch bandage or Rhys-Davies exsanguinator are commonly used to obtain adequate exsanguination in creating a bloodless field.<sup>9</sup> Exsanguination increases the risk of forcing infectious fluid, thrombi or tumor cells into the systemic circulation of the patient.<sup>9</sup> The thrombi can possibly result in causing fatal pulmonary emboli.<sup>77</sup> Exsanguination with an Esmarch bandage or other type of elastic bandage is not recommended in patients with a traumatic injury or a patient who has recently been in a cast to prevent dislodging thrombi.<sup>78</sup>

The CST may be responsible for continuing to elevate the extremity while the anesthesia provider applies an Esmarch bandage. If the Esmarch bandage is not used to exsanguinate an extremity, to attain maximum exsanguination, the arm should be elevated at  $90^{\circ}$  and the leg at  $45^{\circ}$  each for five minutes.<sup>9</sup>

9. The lowest possible cuff pressure should be established to achieve vascular occlusion.<sup>10,25</sup> Nerve and muscle injuries can result from excessive or uneven distribution of pressure under the cuff.<sup>9,50</sup> Nerve injuries can range from temporary minor paresthesia to paralysis; however, the incidence of permanent injury is very low estimated as 0.032% of surgical procedures that involve the use

of a tourniquet.<sup>25,80</sup> The nerve injury is greatest at the distal and proximal edges of the cuff where the shear stress is greatest.<sup>11,25</sup> Nerve injuries are more common in the upper limb versus lower limb.<sup>11</sup> The radial nerve is the most commonly injured nerve in the upper limb followed by the median and ulnar nerves, whereas, the common peroneal nerve is most the most commonly injured nerve in the lower extremity.<sup>11,25</sup> The pathophysiological cause of nerve injury by the use of a tourniquet is believed to be from compression and ischemia with compression playing more of a role in the injury.<sup>11</sup> The prognosis of nerve injuries is good with most injuries healing within six months.<sup>80,81</sup> To assist with avoiding nerve injuries, the CST must confirm that the pressure display on the tourniquet machine is accurate in providing the cuff pressure. There is a correlation between some nerve injuries and faulty pressure displays, resulting in an excessive cuff pressure.<sup>78</sup>

Muscle injuries are uncommon, but can occur due to the ischemia and mechanical distortion of the tissues caused by tourniquets.<sup>11</sup> Muscle is more susceptible to ischemic damage than nerves.<sup>10</sup> Ischemia can result in metabolic and microvascular changes that increase as the time of cuff inflation increases.<sup>81,82</sup> Muscle injuries seem to occur more often in the elderly, most likely due to an increased susceptibility of older skeletal muscle to ischemia and reperfusion injury.<sup>83</sup>

- A. The surgeon and anesthesia provider consider many clinical factors when determining the pressure including size and weight of patient, patient preexisting conditions, extremity circumference and blood pressure.
- B. Studies have supported that *limb occlusion pressure* (LOP) is an effective and safe method for determining the minimum pressure.<sup>7</sup> However, the majority of studies regarding LOP have focused on adult patients with very few studies validating the technique for pediatric patients. Reilly et al. (2009) conducted a blind, prospective randomized controlled trial involving twenty-one patients undergoing a pediatric anterior cruciate ligament reconstructive surgical procedure. Their data confirmed the use of a wide contour cuff and LOP can significantly reduce the mean tourniquet cuff pressure in pediatric patients compared with the standard 250 or 300 mm Hg.<sup>84</sup> Therefore, the risk of tourniquet-related complications may be reduced by use of the LOP method.<sup>84,85</sup> Modern day tourniquet systems have been developed that automatically measure the LOP.<sup>6.25</sup>

A definition of LOP is the minimum pressure required to stop the flow of arterial blood into the limb distal to the cuff.<sup>11</sup> The LOP is determined by gradually increasing the tourniquet pressure until distal blood flow is interrupted.<sup>11</sup>

- 1) The guidelines for determining the LOP for the adult and pediatric patient are:
  - a) The pressure should never exceed  $500 \text{ mm Hg.}^{50}$
  - b) LOP <130 mm Hg add 40 mm Hg.<sup>11</sup>
  - c) LOP between  $131 190 \text{ mm Hg} \text{add } 60 \text{ mm Hg}.^{11}$
  - d) LOP >190 mm Hg add 80 mm Hg. $^{11}$

- e) Pediatric patients add 50 mm Hg. $^{11}$
- f) Frequently monitor the pressure, particularly when the surgeon must reposition the limb.<sup>50</sup> The pressure setting is affected by repositioning the extremity during a procedure.<sup>6</sup> Pressure setting is also affected by changes in the patient's systolic pressure and by cuff width in relation to limb circumference.<sup>6</sup>
- g) The LOP is determined during the patient preoperative appointment or when the blood pressure is stabilized after anesthesia induction.<sup>11</sup>
- h) Odinsson et al. (2006) reported that forty-one percent of the 265 surgeons who responded to a survey reported that a lower tourniquet pressure should be used for pediatric patients and forty surgeons reported that the cuff pressure should be reduced with the use of a wider cuff.<sup>5</sup>
- i) Clarke et al. (2001) studied thirty-one patients undergoing total knee arthroplasty to determine if the use of a tourniquet had any influence on postoperative wound hypoxia. The patients were divided into three groups of ten one group had no tourniquet; second group had a tourniquet applied at 125 mm Hg above mean arterial blood blood pressure and the third group at 250 mm Hg also above mean arterial blood pressure tourniquet increases the postoperative wound hypoxia and recommended that the lowest possible cuff pressure should be used to decrease complications.<sup>79</sup>
- C. Other methods for determining minimum cuff inflation pressure include either by pulse oximetry or by using an ultrasonic blood-flow detector (Doppler stethoscope) to confirm the absence of the arterial pulse.<sup>6,11,50</sup>
- D. The guidelines for tourniquet pressure for the adult are:
  - 1) The pressure should never exceed  $500 \text{ mm Hg.}^{50}$ 
    - 2) Fifty mm Hg above the patient's systolic blood pressure for upper extremities.<sup>64</sup>
    - 3) 100 mm Hg above the patient's systolic blood pressure for lower extremities.<sup>64</sup>
    - 4) Frequently monitor the pressure, particularly when the surgeon must reposition the limb.<sup>50</sup> The pressure setting is affected by repositioning the extremity during a procedure.<sup>6</sup> Pressure setting is also affected by changes in the patient's systolic pressure and by cuff width in relation to limb circumference.<sup>6</sup>
    - 5) Odinsson et al. (2006) reported that forty-one percent of the 265 surgeons who responded to a survey reported that a lower tourniquet pressure should be used for children and forty surgeons reported that the cuff pressure should be reduced with the use of a wider cuff.<sup>5</sup>

- 6) Clarke et al. (2001) studied thirty-one patients undergoing total knee arthroplasty to determine if the use of a tourniquet had any influence on postoperative wound hypoxia. The patients were divided into three groups of ten one group had no tourniquet; second group had a tourniquet applied at 125 mm Hg above mean arterial blood pressure and the third group at 250 mm Hg also above mean arterial blood pressure tourniquet increases the postoperative wound hypoxia and recommended that the lowest possible cuff pressure should be used to decrease complications.<sup>79</sup>
- E. A thigh tourniquet should not be inflated with the leg flexed followed by straightening the leg which fixates the sciatic nerve to the femur causing severe stretching of the nerve.
- 10. When the surgical team performs the time-out procedure this also serves in verifying that the tourniquet has been positioned on the correct extremity.<sup>6,86</sup>
  - A. In 2010, the Pennsylvania Patient Safety Advisory reported two instances of the cuff being applied to the wrong extremity.<sup>6</sup>
    - 1) A patient was transported to the OR to undergo a right knee arthroscopy. A tourniquet was placed on the left leg and inflated by the RN who also performed the skin prep on the left leg. The surgeon performed the time-out confirming "right knee". The tourniquet was immediately deflated and positioned on the right leg.
    - 2) A tourniquet was positioned on the incorrect leg, even though the site for the incision had been marked on the correct leg. The surgical team did not perform the time-out procedure and the incision was made in the incorrect knee. When the surgeon noticed there was a lack of an incision mark the procedure was discontinued.
- 11. The cuff inflation time should be as minimal as possible. Extended application time can cause *compartment syndrome*, muscle ischemia, temporary or permanent limb paralysis or weakness due to nerve damage and tissue bruising.<sup>6.50</sup> Reports of temporary or persistent nerve damage are uncommon in the literature, but nerve injuries do occur particularly when the cuff pressure is high and/or after lengthy cuff inflation.<sup>87</sup> According to the literature, the risk of nerve injury is between 0.1 and 7.7%.<sup>5,88,89</sup> Horlocker et. al (2006) reported a strong connection between nerve injury and tourniquet time with a threefold increase in the risk of neurological complications for each thirty minutes of increase in cuff inflation. Additionally, the length of uninterrupted cuff inflation also increased the chances of neurological complications.<sup>88</sup> In most cases of nerve injury, the damage occurs to the section of nerve that is directly under or near the edges of the cuff.<sup>65</sup>

Muscle ischemia generally occurs within one to three hours.<sup>6</sup> A rare, but serious complication of muscle ischemia is acute compartment syndrome. Extended tourniquet time causes a decrease in tissue pH, increases capillary permeability and prolongs clotting; in combination, these can lead to the development of acute compartment syndrome.<sup>78</sup> The first symptom the patient

experiences is pain that continues to increase and is not relieved by pain medications.<sup>90</sup> Other symptoms that eventually develop are absent pulses, muscle weakness, paresthesia and tense skin; if left untreated irreversible paralysis can occur.<sup>90</sup> The only treatment is a fasciotomy surgical procedure.<sup>90</sup> Preventative measures include during the preoperative assessment of the patient confirm if the patient and/or family has a history of compartment syndrome symptoms; as previously stated, cuff inflation time should be as minimal as possible; and not applying a cast prior to cuff deflation.<sup>90</sup>

There is no established rule for how long a tourniquet may remain safely inflated and the length of time may vary due to several factors including age of patient, health status including pre-existing conditions and vascularity of the extremity.<sup>6.10.24</sup> The following are general recommendations regarding cuff inflation.

- A. Tourniquet inflation should be performed under the direction of the surgeon who coordinates with the anesthesia provider for the purposes of patient management during the rapid physiological changes that are caused prior to and after limb exsanguination and cuff inflation.<sup>11</sup>
- B. The cuff should be rapidly inflated by the tourniquet machine; rapid inflation simultaneously compresses the arteries and veins preventing the veins from filling before compression of the arteries.<sup>11</sup>
- C. For adults, sixty minutes is the recommended inflation time for upper extremities and ninety minutes for lower extremities, and sixty minutes for both upper and lower extremities for the pediatric patient.<sup>10,91</sup> Tissue edema begins to develop once the tourniquet time exceeds sixty minutes.<sup>10</sup> The surgeon should be notified when the cuff has been inflated for a minimum of two hours.<sup>11</sup> When the recommended time limit has been reached, the surgeon may deflate the cuff for ten to fifteen minutes to allow for re-perfusion of the extremity and then the cuff is reinflated for another time period, e.g., sixty or ninety minutes.<sup>11</sup> For pediatric patients, an inflation time of less than seventy-five minutes has been recommended for the lower extremities.<sup>10</sup> The surgeon may want to re-exsanguinate the limb prior to reinflation to avoid venous thrombosis; the CST in the first scrub role should have a sterile Esmarch bandage ready to use on the sterile field or available in the OR.
  - Odinsson et al. (2006) reported that of the 265 surgeons that responded to the survey, eighty percent deflated the tourniquet during surgery for fifteen minutes if the surgical procedure lasted >two hours and thirteen percent did not deflate the tourniquet if the procedure lasted >two hours.<sup>5</sup> The authors concluded that surgeons should not exceed two hours of ischemia time to avoid the occurrence of permanent nerve damage and to reduce the patient's pain from the tourniquet.<sup>5,25</sup>
- 12. To ensure patient safety, the tourniquet system alarm should not be turned off or turned down so far that the surgical team cannot heart it. The alarm can be activated by cuff leaks, excessively low or high cuff pressures, kinks in tubing, mechanical failure, and prolonged tourniquet time.<sup>6,25</sup>

- 13. If the location of the cuff needs to be adjusted or changed, the cuff and underlying padding should be completely removed, new padding placed and the cuffed reapplied.<sup>52</sup> The cuff should never be repositioned by pulling it up or down or rotating while on the extremity; this can cause a shearing injury to the skin.<sup>41,52</sup>
- 14. During the procedure, the CST in the assistant circulator role should help in monitoring the cuff pressure display and time. The surgeon may request the tourniquet pressure to be adjusted during the procedure. If any changes occur to the cuff pressure, the CST should immediately report it to the surgeon since this can be an indicator of a cuff malfunction.
- 15. Tissue may be prone to drying due to the heat generated by the surgical lights or use of powered surgical instruments since the heat cannot be dispersed by extremities that are affected by a tourniquet.<sup>78</sup> To reduce the risk low-power surgical lights are recommended and the CST in the first scrub role should occasionally wet the tissues with irrigating fluid. Additionally, when the surgeon is using a powered surgical instrument such as a saw, the CST should apply drops of irrigating fluid to the area that is being cut to reduce the heat generated by the powered instrument.
- 16. The cuff(s) should be deflated at the end of the surgical procedure; the CST should confirm with the surgeon and/or anesthesia provider that the cuff(s) can be deflated.
  - A. The CST should follow the manufacturer's IFU for deflation.
  - B. Upon deflation the cuff and cast padding should be immediately removed.<sup>6,50,63</sup> The deflated tourniquet and cast padding should not be left on the patient as he/she is transported to the PACU or another department. The tourniquet and padding could contribute to poor venous return causing venous pooling and thrombosis.
  - C. Deflation of the cuff prior to or after wound closure is a subject that has not been definitively decided upon and studies have various conclusions. Therefore, it cannot be overemphasized for the CST to confirm with the surgeon if he/she wants the cuff deflated.
    - Cuff deflation results in an immediate 10% increase in extremity circumference due to vessels being refilled and hyperemia.<sup>9</sup> The results in an increase in compartmental pressure in the extremity. During the first postoperative day the initial extremity circumference can increase up to 50% and the swelling remain for up to six weeks.<sup>92</sup> The surgeon may request the cuff to be deflated prior to achieving hemostasis and performing wound closure to allow the extremity to be reperfused and swelling to take place before the sterile dressing and cast are applied.<sup>9</sup> This may assist in reducing the complications associated with compartment syndrome.<sup>90</sup>
    - 2) Ishii and Matsuda (2005) studied perioperative blood loss as related to cuff release before and after wound closure in fifty-five patients during 60 total knee arthroplasties. The cuff was deflated in thirty procedures of twenty-nine patients and after wound closure in thirty procedures of twenty-six patients. The authors

reported no complications occurred during the procedures and no patients required blood transfusion. The reported mean total blood loss for all the procedures was 819 mL.<sup>93</sup> Total blood loss in the group with cuff release before wound closure was 906 mL and in the group with cuff release after wound closure 731 mL.<sup>93</sup> The authors concluded that the cuff should be deflated after wound closure during total knee arthroplasties and to apply a pressure dressing that reduces the blood loss.<sup>93</sup>

- 3) Thorey et al. (2008) conducted a randomized prospective study involving twenty patients who underwent simultaneous bilateral total knee arthroplasty. Technique A involved operating on one knee with cuff deflation and hemostasis before wound closure and Technique B on the other knee involved cuff deflation after wound closure and application of the pressure dressing. The results showed no significant difference in blood loss between the two techniques as well as no increase in postoperative complications.<sup>94</sup> However, there was a significant difference in operating time with Technique B having a shorter length to time.<sup>94</sup> The authors recommended tourniquet release after wound closure to reduce operating time and risks of extended anesthesia.<sup>94</sup>
- D. There may be instances of when the surgeon requests the tourniquet to be deflated intraoperatively. Marson and Tokish (1999) studied whether an inflated tourniquet affected the intraoperative patellofemoral tracking during total knee arthroplasty. The authors concluded that use of an inflated tourniquet could alter intraoperative patellofemoral tracking and the tourniquet should be deflated to contribute to accurate tracking before proceeding with the lateral release step of the procedure.<sup>95</sup>

#### **Guideline IV**

The CST should be knowledgeable of the safety precautions that are unique to the use of IVRA, also referred to as a Bier block.

- 1. During the preoperative assessment of the patient, allergies to local anesthetics should be confirmed which can determine if IVRA will be utilized.<sup>51</sup>
- 2. When the anesthesia provider is employing IVRA, the CST should assist in confirming the immediate availability of the drugs that are required for treating adverse systemic reactions to the local anesthesia in the event of tourniquet failure and be prepared to assist the anesthesia provider.<sup>50</sup>
  - A. Accidental introduction of the local anesthetic into the patient's systemic circulation can quickly affect the central nervous and cardiac systems. If the patient is sedated but awake symptoms he/she may communicate to the surgical team include dizziness, drowsiness, and tinnitus. However, if the patient is under general anesthesia signs and symptoms that the anesthesia provider will recognize include bradycardia and respiratory depression.<sup>78</sup>
  - B. The primary cause of for adverse reactions occurring is technical error.<sup>78</sup> The following are instances that may result in the patient experiencing a

toxic reaction; these are from McEwen (2018), *Tourniquet Safety: Mechanisms and Prevention of Injuries.* 

- 1) Inadequate pressurization of the cuff prior to injection of the local anesthetic allowing the agent to leak underneath the cuff into the systemic circulation.
- 2) Inadequate exsanguination of the extremity occurs prior to the injection of the local anesthetic. The veins distal to the cuff that are not adequately exsanguinated will be infiltrated by the local anesthetic increasing the venous pressure to a level that allows the local anesthetic to escape beneath the cuff and into the systemic circulation.
- 3) An accidental, sudden deflation of the cuff allows the local anesthetic to quickly enter the system circulation.
- 3. IVRA is usually performed with a dual-bladder cuff, but two single cuffs may be used.
  - A. A higher cuff pressure may be required since the dual-bladder cuffs or two single cuffs are narrower in width; however, the pressure should still be based upon the LOP measurement.<sup>51</sup>
  - B. Since the majority of patients receive monitored anesthesia care during IVRA and will be awake, but sedated, the CST in the assistant circulator role should explain everything to the patient that is occurring including the tourniquet equipment and any tourniquet machine sounds or alarms he/she may hear.
  - C. Each bladder of the dual-bladder cuff must be connected to the tourniquet system by the CST. If a dual-cuff control valve is used between the tourniquet machine and cuffs, the CST should be familiar with the connection and how to operative the valve.<sup>51</sup> The CST should consult the manufacturer's instruction manual.

The CST should be aware that tourniquet systems have two independent channels that control the pressures of both cuffs during a procedure involving IVRA.<sup>51</sup> This is important when one cuff is being inflated, deflated and regulated during the procedure. Since this requires two hose assemblies, the CST should clearly know which cuff is connected to the first and second cuff channels on the tourniquet machine.

D. The CST should clearly understand the sequence of cuff inflation and deflation to prevent systemic complications.<sup>10</sup> After the limb is exsanguinated the proximal cuff should be inflated and the anesthesia provider will then inject the local anesthetic; usually, the proximal cuff is inflated first, but the CST should confirm this with the surgeon and anesthesia provider.<sup>6,51</sup> The cuff should not be deflated for at least twenty minutes after the anesthetic has been injected.<sup>6,50</sup>

After twenty to thirty minutes, the surgeon and/or anesthesia provider may request the proximal cuff to be deflated and the distal cuff inflated; however, the CST must remember not to deflate the proximal cuff until the distal cuff is fully inflated.<sup>6,51</sup> There are tourniquet systems

that have an IVRA safety lockout embedded that prevent the unintentional deflating of both bladders during a dual-cuff procedure.<sup>51</sup> Inflating the distal cuff may also provide the patient with additional comfort since the tissues under the distal cuff have been anesthetized.<sup>51</sup>

# **Guideline IV**

# Documentation of the use of the tourniquet should be included in the patient's OR record.

- 1. Documentation should include the following:
  - A. Site of cuff placement.<sup>6.50</sup>
  - B. Name of person who applied the cuff.
  - C. Type of skin protection that was applied.
  - D. Systemic reactions to ischemia and reperfusion.<sup>58</sup>
  - E. Initial blood pressure of the patient after the cuff is inflated.
  - F. Beginning/original cuff inflation and limb occlusion pressures.<sup>50</sup>
  - G. Preoperative and postoperative assessment of the integrity of the skin.
  - H. Description of adverse events that occur with the tourniquet system or patient.
    - 1) If an adverse event occurs, the time the patient's symptoms began and ended should be documented.
    - 2) The patient's symptoms should be documented.
    - If a malfunction of the tourniquet system is the cause of a patient injury or death, the information should be reported to the manufacturer and U.S. Food and Drug Administration (FDA) according to the requirements of the Safe Medical Devices Act of 1990 (Public Law 102-629).<sup>96</sup>
  - I. HDO's identification number and manufacturer's serial number and model number.
  - J. Preoperative and postoperative assessment of the extremity including pulses distal to the tourniquet.<sup>58</sup>
  - K. What time the surgeon was informed of how long the cuff has been inflated. Times cuff was inflated and deflated, including intraoperative deflation and inflation times.<sup>50</sup> The length of the intraoperative deflation should be recorded as well.<sup>96</sup>

## **Guideline V**

Non-disposable (reusable) cuffs and tubing should be cleaned and decontaminated between patient uses according to manufacturer's instructions and central sterile supply department policy. Additionally, the tourniquet system with all components should be properly stored after disinfecting and between uses.<sup>25,97</sup>

- 1. If the cuff cannot be adequately cleaned it should be discarded.<sup>97</sup>
- 2. The cuff should be cleaned with an EPA-registered intermediate-level tuberculocidal disinfectant solution in lukewarm water.<sup>97</sup> If there are dried blood and/or body fluids on the cuff a soft hand brush should be used to remove the infectious matter to prevent cross-contamination.<sup>97</sup> The cuff should be thoroughly rinsed of the cleaning agent to protect the patient's skin from irritation, prevent

the patient from experiencing an allergic reaction and avoid decreasing the life of the cuff.<sup>97</sup>

- 3. The tubing and pressure device should be cleaned with an EPA-registered intermediate-level tuberculocidal disinfectant solution in lukewarm water.<sup>97</sup> The open end of the tubing should not be immersed in the water/disinfection solution; introduction of the solution into the ports can damage the tubing and contribute to microbial growth.<sup>25,97</sup> Additionally, the solution from the tubing can enter the cuff and upon cuff deflation droplets of the solution are forced into the tourniquet regulator ultimately damaging the system.<sup>97</sup>
- 4. The clean cuff and tubing should be dried according to manufacturer's instructions. The instructions may require the cuff and tubing to drip dry at room temperature or wiped dry with a clean, non-linting cloth to prevent the tubing from drying out and cracking.<sup>25,97</sup>
- 5. After cleaning and drying the cuff and tubing both should be immediately connected to the tourniquet system and tested for pneumatic leakage.<sup>97</sup>
- 6. The tourniquet system with components should be placed in a storage area of the surgery department that is dust-free and clean, and the storage area meets the temperature and humidity requirements of manufacturer. Additionally, it is recommended that the tourniquet system is covered such as with a reusable clear, plastic cover. The manufacturer's operating guide should be included with the tourniquet system in the storage area.

The majority of tourniquet systems are electrical that contain a backup battery that charges while the unit is plugged in; therefore, when the unit is in storage it should be plugged in.

# **Guideline VI**

The surgery department should involve a multi-disciplinary team in the selection and purchase of tourniquet systems to ensure that the systems meet the demands of the surgical specialties that require the use of a tourniquet during specific procedures. The team should include surgeon(s), anesthesia provider(s), risk management, purchasing department, biomedical department, OR manager, CST(s), and RN(s).

- In the U.S., pneumatic tourniquet systems are FDA regulated devices; they are regulated as a Class I medical device under 21 CFR 878.5910 Pneumatic Tourniquet (Title 21 Food and Drugs; Part 878 General and Plastic Surgery Devices; Section 5910 Pneumatic Tourniquet).<sup>98</sup> The following are recommended questions to forward to a vendor prior to purchasing a tourniquet system. A thru C are questions taken directly from McEwen (2018), FDA Requirements for Pneumatic Tourniquets in the United States.
  - A. Is the pneumatic tourniquet's manufacturer registered as an establishment with the FDA and has the manufacturer device listed the pneumatic tourniquet product with the FDA?
    - 1) The manufacturer should provide the Establishment Registration Number and description and the Device Listing Number.

- B. Does the labeling and packaging of the pneumatic tourniquet product comply with all relevant requirements specified by the FDA?
  - 1) The manufacturer should provide a copy of the labeling that includes the contraindications, IFU, precautions, prescription device statement and warnings.
- C. Does the pneumatic tourniquet's manufacturer have an appropriate and certified quality system for the design, manufacture, installation and servicing of its pneumatic tourniquet products, and management and control of these processes?
  - 1) The manufacturer should provide a copy of the quality system certificate or equivalent evidence of quality system compliance with 21 CFR 820.
- D. Does the pneumatic tourniquet system contain the following features:
  - 1) Embedded automatic cuff leak detection.
  - 2) Embedded automatic LOP measurement.
  - 3) Embedded automatic cuff testing capability.
  - 4) Releasable application handles rather than tie ribbons.
  - 5) Safety interlock to prevent inadvertent deflation of both cuffs during a procedure involving IVRA.
- E. Will the surgery department be allowed to use a "loaner" pneumatic tourniquet system to test as well as use during surgical procedures for a prescribed period of time?

### **Guideline VII**

# The surgery department should review the policies and procedures (P&P) regarding safe use of pneumatic tourniquets on an annual basis.

- 1. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, RNs, risk management and infection control officer.
  - A. The surgery department should document when the P&Ps were reviewed, revision completed (if necessary) and who participated in the review process.
  - B. Tourniquets should be included in a routine documented equipment inspection program and preventative maintenance.<sup>6,25,50</sup> Procedures should be established addressing documentation and record keeping at regular intervals of the biomedical inspection and preventive maintenance of the tourniquet system(s) that are in the surgical suite; a 6-month inspection interval is recommended.<sup>50</sup> Documentation of each tourniquet system should include the assigned biomedical or HDO identification number, manufacturer's serial number, date of inspection and preventive maintenance and comments as to the effectiveness level of the equipment.<sup>97</sup> Additionally, every month, a designated individual, CST or RN, should test the tourniquet systems by connecting the controller to a gauge to verify the pressure accuracy at 300 mm Hg.<sup>50</sup>

The pneumatic system(s) should be listed on the facility's inventory of biomedical equipment to facilitate identification and location

of units affected by a manufacturer's recall or other notification that require action by the HDO.<sup>6</sup>

- C. If a pneumatic tourniquet malfunctions and is determined to be the root cause of a patient injury or contributing factor to a patient death, the HDO is required to report the incident and related information to the manufacturer of the tourniquet system and to the U.S. Food and Drug Administration which is required according to the Safe Medical Devices Act of 1990.<sup>99</sup>
- 2. CSTs should be familiar with the P&Ps for safe use of pneumatic tourniquets. The orientation of new employees should include reviewing the P&Ps.

# **Standard of Practice VIII**

# CSTs should complete continuing education to remain current in their knowledge of the safe use of tourniquets.<sup>100</sup>

- 1. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; information is practical, rather than academic; and the learner is actively involved in the learning process.<sup>101</sup>
- 2. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
  - A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion and audience discussion providing suggestions for reinforcing safe use of tourniquets.
  - B. Other proven educational methods include interactive training videos and computerized training modules and teleconferences.
  - C. The continuing education should be delivered over short periods of time such as in modules and not in a one-time lengthy educational session.
- 3. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
- 4. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.
  - A. Unique to the continuing education regarding tourniquets the CST should completing training on application of the cuff, operating the tourniquet system and monitoring the pressure, troubleshooting the tourniquet system, and completing the patient documentation.

# **Competency Statements**

Competency Statements	Measurable Criteria
1. CSTs are knowledgeable of the	1. Educational standards as established
contraindications, patient hazards, risks	by the Core Curriculum for Surgical
and safety factors associated with the use	Technology. <sup>102</sup>
of pneumatic tourniquets.	
	2. The didactic subject of pneumatic
2. CSTs are qualified to assist the	tourniquets is included in a CAAHEP
surgeon and/or anesthesia provider in the application of the tourniquet.	accredited surgical technology program.
	3. Students demonstrate knowledge of
3. CSTs are qualified to apply the	the pneumatic tourniquet during clinical
padding and tourniquet cuff to the	rotation.
patient's extremity under the supervision	
of the surgeon and/or anesthesia provider.	5. CSTs complete continuing education
	to remain current in their knowledge and
4. CSTs are qualified to operate the	skills in the safe use of pneumatic
pressure device by establishing the	tourniquets. <sup>100</sup>
pressure setting.	

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# Glossary

Bier block: See intravenous regional anesthesia.

*Compartment syndrome*: Muscles are organized into compartments and the walls of the compartments are formed by fascia. After an injury or use of a tourniquet fluid can accumulate in one or more compartments. The fibrous fascia does not easily expand the pressure increases within the compartment(s) preventing adequate blood flow that leads to ischemia and possible severe tissue damage or necrosis if not immediately treated by performing a fasciotomy surgical procedure.

*Exsanguination*: The act of removing blood and tissue fluids from an extremity.

*Intravenous regional anesthesia*: A type of regional anesthesia whereas an extremity is exsanguinated, a tourniquet is applied and the cuff inflated the anesthesia provider injects a local anesthetic into the extremity; also called a Bier block.

*Knee arthroscopy*: A surgical procedure that involves the intraarticular insertion of an arthroscope to view the anatomical structures of the knee joint for diagnostic purposes and/or performing minimally invasive surgery such as a meniscectomy.

*Limb occlusion pressure (LOP)*: A definition of LOP is the minimum pressure required to stop the flow of arterial blood into the limb distal to the cuff.

*Pneumatic tourniquet*: A device that uses air or nitrogen to inflate a compressing device called the cuff that is used to compress the arteries and veins of an extremity to produce a bloodless surgical site.

*Total knee arthroplasty*: A surgical procedure whereby the damaged or diseased knee joint is replaced with prostheses. Several cuts are made with a saw on the end of the femur and the femoral component is placed; the end of the tibia is cut to create a "shelf" and the tibial component is placed; and if the underside of the patella is damaged, a plastic "button" is positioned. The prostheses may be uncemented or cemented.

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