Tourniquet-Related Hazard Reports
1998 – 2008

Note: Selected tourniquet-related hazard reports published between 1998-2008 are summarized below. While specific products may be identified in some of the reports, the intent of many of the reports may not necessarily be to implicate those specific products, and the problem and/or results may occur with similar products of other manufacturers.

Abstracts

Pneumatic Tourniquet Cuffs: FDA Issues Safety Advice

Product Identifier:
Pneumatic Tourniquet Cuffs *[Consumable]*
Units distributed in the U.S.
Problem: In an April 2007 broadcast of the video series FDA Patient Safety News, FDA reviewed safety issues related to use of pneumatic tourniquet cuffs. The effectiveness of the tourniquet can be compromised if the cuff becomes crinkled, folded, or bent. This problem can cause insufficient or inconsistent pressure to be applied, resulting in poor control of blood flow to the affected area.
Action Needed: FDA recommends taking the following precautions:
(1) Select a cuff that will overlap between 3 and 6 inches when used on the patient.
Too much overlap causes increased pressure and wrinkling of the underlying soft tissue.
(2) Before applying the cuff to the patient, inspect it for rips or holes and ensure that the tubing connecting the cuff to the tourniquet system is not kinked or occluded.
(3) When applying the cuff, ensure that it is smooth, since wrinkles or tunneling could damage the underlying skin and soft tissue. If the manufacturer's instructions suggest it, use soft, wrinkle-free padding between the cuff and the skin for added protection.
(4) If the patient experiences uncontrolled bleeding at the site, note that increasing the pressure may not be effective if the cuff does not allow pressure to be applied properly. Before increasing the pressure, check the cuff to ensure that it is inflated properly, is not damaged, and does not have wrinkles or crinkling.
(5) If the location or position of the cuff needs to be adjusted, remove the cuff and reapply it. Never pull the cuff up or down while it is on the limb.
Source: United States. Food and Drug Administration. Safe use of pneumatic tourniquet cuffs. In: FDA patient safety news [video series online]. No. 62. 2007 Apr [cited 2007 Apr 2]. Available from Internet: http://www.accessdata.fda.gov/psn/transcript.cfm?show=62#7.

Odinsson A, Finsen V. Tourniquet use and its complications in Norway. J Bone Joint Surg Br 2006 Aug;88(8):1090-2.

Product Identifier:
(1) Pneumatic Tourniquets; (2) Esmarch Bandages
Abstract: The authors surveyed clinicians to determine how tourniquets are used in clinical practice in Norway and to obtain data on the incidence and nature of complications associated with tourniquet use. Over a 2-year period, 265 orthopedic surgeons from 71 hospitals in Norway performed approximately 63,484 surgical procedures using tourniquets. 72% of physicians used pneumatic tourniquets, 14% of physicians used Esmarch bandages as tourniquets, and 14% of physicians did not indicate the types of tourniquets used. 80% of physicians stated that they deflated the tourniquet during surgery (median deflation time was 15 min) if the procedure lasted >2 hr, 13% of physicians stated that they did not deflate the tourniquet if the procedure lasted >2 hr, and 7% of physicians stated that none of their surgical procedures lasted >2 hr. 108 surgeons stated that a lower tourniquet pressure should be used for children, and 40 surgeons stated that pressure could be reduced with use of a wider cuff. 26 complications occurred over the study period. 6 complications involved compartment syndrome or deep vein thrombosis, both of which were more likely attributable to the injury or the surgery, rather than to use of the tourniquet. 2 complications were excluded from analysis because further information could not be obtained. The remaining 18 complications included 3 cases of blistering and skin necrosis and 15 upper- or lower-limb nerve complications, 2 of which were permanent. Of the remaining 13 nerve complications, which resolved spontaneously within 6 months of surgery, 6 cases involved paresis, 6 cases involved sensory disturbance, and 1 case involved complete sensory and motor palsy in the arm. The authors conclude that until further tourniquet design improvements are made, physicians should not exceed 2 hr of ischemia time to reduce the occurrence of permanent nerve damage.
Source: Odinsson A, Finsen V. Tourniquet use and its complications in Norway. *J Bone Joint Surg Br* 2006 Aug;88(8):1090-2.

Al-Ghamdi AA. Bilateral total knee replacement with tourniquets in a homozygous sickle cell patient. *Anesth Analg* 2004 Feb;98(2):543-4.

Product Identifier:
ATS 2000 Tourniquets
Manufacturer: Zimmer Orthopaedic Surgical Products [409954], 200 W Ohio Ave PO Box 10, Dover OH 44622-0010
Abstract: The author reports the use of an ATS 2000 tourniquet for bilateral total knee replacement in a 27-year-old man with a history of severe osteonecrosis attacks as a complication of sickle cell disease. The night before the operation, an infusion of lactated Ringer's solution was started at 120 mL/hr. The patient received 1.0 g of intravenous (IV) ceftazidime and 10 mg of diazepam orally 60 min preoperatively. The operating room was warmed and a heating mattress was used to adjust body temperature. After preparation, the tourniquet was applied to the right knee and was inflated to 300 mm Hg for 97 min. After deflation, the tourniquet was immediately moved to the left knee and inflated for 69 min. The patient was stable throughout the

procedure and received 2 packed red blood cell (PRBC) units in the postanesthesia care unit (PACU). Approximately 800 mL of blood had accumulated when the patient left the PACU. The patient's temperature was maintained with an artificial warming device, and he received O_2 and IV meperidine. Following transfer to the general ward, the patient received another PRBC unit, supplemental O_2, and analgesia. 6 arterial blood samples taken during tourniquet inflation and deflation showed no significant increase in sickled cells compared to preoperative samples and no major changes in blood gas volume. The patient was doing well at 6 months. The author concludes that a patient with sickle cell disease should not be denied an operative procedure using a tourniquet if the procedure is vital and when care is taken to minimize sickling.

Source: Al-Ghamdi AA. Bilateral total knee replacement with tourniquets in a homozygous sickle cell patient. *Anesth Analg* 2004 Feb;98(2):543-4.

Comment: While a specific product is identified in this report, ECRI believes that the intention of the article was not, necessarily, to implicate this particular product and that this problem and/or these results may occur with similar products of other manufacturers.

Estebe JP, Le Naoures A, Chemaly L, et al. Tourniquet pain in a volunteer study: effect of changes in cuff width and pressure. *Anaesthesia* 2000 Jan;55:21-6.

Product Identifier:
Pneumatic Tourniquets; Contour Arm Cuffs: (1) 7 cm Proximal Double-Bladder, (2) 14 cm Single-Bladder Low-Pressure; (3) Pneumatic Tourniquets

Manufacturer: (1 and 2) Zimmer Inc [102165], PO Box 708, Warsaw IN 46581-0708; (3) Manufacturer not identified in article

Abstract: The authors compared pneumatic tourniquet pain tolerance using 2 tourniquet cuff widths at 100 mm Hg above systolic blood pressure and at the lowest effective occlusive pressure in 20 volunteers. A wide and a narrow cuff were placed on each arm of the volunteers, who were divided into 2 groups of 10 volunteers each. In the pressure group, the tourniquets were inflated to 100 mm Hg above systolic blood pressure, and in the saturation group, the tourniquets were inflated until the arterial pulsation disappeared at 10 mm Hg. Mean occlusion pressure in the pressure group was 258 ±12 mm Hg and 260 ±8 mm Hg with the narrow and wide cuffs, respectively; mean occlusion pressure in the saturation group was 202 ±4 mm Hg and 147 ±4 mmHg with the 2 cuffs, respectively. The authors state that, in the pressure group, the mean visual analog scale (VAS) scores with the wide cuff were significantly higher and increased faster than the VAS scores with the narrow cuff. In the saturation group, the mean narrow cuff VAS scores increased significantly higher and faster than the wide-cuff scores. Pain was tolerated with the narrow and wide cuffs for 36 ±6 min and 26 ±3 min, respectively, in the pressure group, and for 24 ±9 min and 28 ±5 min, respectively, in the saturation group. The authors conclude that a wide-cuff pneumatic tourniquet is more effective in the occlusion stage than a narrow cuff and that it is less painful when pressure is limited to arterial pulse loss. The authors add that a wide cuff is more painful if pressure is adjusted to 100 mm Hg
above systolic blood pressure.

Source: Estebe JP, Le Naoures A, Chemaly L, et al. Tourniquet pain in a volunteer study: effect of changes in cuff width and pressure. *Anaesthesia* 2000 Jan;55:21-6.

Tsavellas G, Ranaboldo CJ. Tourniquet use during varicose vein surgery: a survey of current practice among Wessex surgeons. *Ann R Coll Surg Engl* 2000 Mar;82(2):116-9.

Product Identifier:
(1) Pneumatic Tourniquets; Tourniquet Cuffs: (2) Rhys-Davies, (3) Roll-On Inflatable

Abstract: The authors assessed the views and current practice of surgeons regarding the use of pneumatic tourniquets during varicose vein surgery. There were 79 respondents to a questionnaire that asked whether the surgeons used a tourniquet during surgery for primary recurrent varicose veins. The frequency of use was graded as regularly, occasionally, and never. 55 of 79 respondents stated that they never used a tourniquet, 10 of 79 respondents stated that they did so occasionally, and 14 of 79 respondents stated that they did so regularly. Among the 24 regular and occasional tourniquet users, 2 reported skin burns attributed to contact with a hot autoclaved rubber wedge as used with a roll-on tourniquet. 22 respondents reported no complications resulting from tourniquet use. The authors conclude that because of tourniquets' safety and benefits, the use of tourniquets during varicose vein surgery should be more widespread.

Source: Tsavellas G, Ranaboldo CJ. Tourniquet use during varicose vein surgery: a survey of current practice among Wessex surgeons. *Ann R Coll Surg Engl* 2000 Mar;82(2):116-9.

Aglietti P, Baldini A, Vena LM, et al. Effect of tourniquet use on activation of coagulation in total knee replacement. *Clin Orthop* 2000 Feb;(371):169-77.

Product Identifier:
(1) Surgical Tourniquets; (2) M.B.K Unilateral Primary Cemented Total Knee
Prostheses

Manufacturer: (1) Manufacturer not identified in article; (2) Zimmer Inc [102165], PO Box 708, Warsaw IN 46581-0708

Abstract: The authors compared the hypercoagulative state occurring during total knee replacement surgery with and without pneumatic tourniquets in 2 groups of 10 patients who received unilateral primary cemented total knee prostheses. Blood samples were collected 1 hr before anesthesia, after bone cuts, 2 minutes after tourniquet deflation in the tourniquet group and after cementing the prosthesis in the nontourniquet group, and 1 hr after surgery. Prothrombin fragments 1 + 2 increased from 1.4 nmol/L to 7.2 nmol/L in the tourniquet group and from 1.6 nmol/L to 9.3 nmol/L in the nontourniquet group. Thrombin and antithrombin complexes increased from a baseline of 10.6 to 18.0 after bone cuts, 41.8 after tourniquet deflation, and 73.0 after surgery in the tourniquet group and from a baseline of 6.2 to 33.0 after bone cuts, 88.0 after cementation, and 117.0 after surgery in the nontourniquet group. The D-dimer value 1 hr after surgery was 1,241 in the tourniquet group compared to 751 in the nontourniquet group. The authors conclude that use of surgical tourniquets canenhance fibrinolysis and prevent deep vein thrombosis in patients undergoing total knee replacement surgery.

Source: Aglietti P, Baldini A, Vena LM, et al. Effect of tourniquet use on activation of coagulation in total knee replacement. *Clin Orthop* 2000 Feb;(371):169-77.

Improper use of tourniquet during carpal tunnel surgery allegedly leads to ulnar nerve injury. *Med Malpract Verdict Settlements* 1999 Dec;15(12):36.

Product Identifier:
Tourniquets
Abstract: A legal case is described in which the plaintiff, a 45-year-old woman, alleged that the use of a tourniquet during a right-side carpal tunnel release procedure performed by the defendant rendered her hand disabled. The plaintiff claimed that her preexisting ulnar neuropathy was exacerbated by O_2 deprivation caused by excessive tourniquet pressure. The plaintiff further claimed that her preexisting condition contraindicated tourniquet use. The defendants contended that it is acceptable practice to use tourniquets in carpal tunnel releases. The jury returned a defense verdict. (*Patricia McGrath v. Joseph Suarez, M.D.; Henry Sasso, M.D., and Seaview Anesthesiology Associates*, Richmond County {NY} Supreme Court, Index No. 1927/90.)
Source: Improper use of tourniquet during carpal tunnel surgery allegedly leads to ulnar nerve injury. *Med Malpract Verdict Settlements* 1999 Dec;15(12):36.

Coleman MM, Peng PW, Regan JM, et al. Quantitative comparison of leakage under the tourniquet in forearm versus conventional intravenous regional anesthesia. *Anesth Analg* 1999 Dec; 89(6):1482-6.

Product Identifier:
(1) 14 cm Double Tourniquets; (2) 22 G Cannulae
Manufacturer: (1) Zimmer Inc [102165], PO Box 708, Warsaw IN 46581-0708; (2) Manufacturer not identified in article
Abstract: The authors quantitatively compared leakage under a double tourniquet during intravenous regional anesthesia (IVRA) in the forearm and upper arm in 14 patients. Leakage in the upper arm and forearm was 10% ±20% and 6% ±12%, respectively. A mean forearm leakage of 59% ±11% and a mean upper-arm leakage of 70% ±7% were recorded 3 min after deflation. A forearm leakage of 69% ±11% and an upper-arm leakage of 82% ±5% were observed 20 min after deflation. The authors conclude that leakage under the double tourniquet is similar in both forearm and upper-arm IVRA and that, with lower dose requirements, forearm IVRA will increase
the safety margin of the IVRA technique.
Source: Coleman MM, Peng PW, Regan JM, et al. Quantitative comparison of leakage under the tourniquet in forearm versus conventional intravenous regional anesthesia. *Anesth Analg* 1999 Dec; 89(6):1482-6.

Mohler LR, Pedowitz RA, Lopez MA, et al. Effects of tourniquet compression on neuromuscular function. *Clin Orthop* 1999 Feb;359:213-20.

Product Identifier:
Inflatable Thigh Tourniquets
Abstract: The authors examined 84 rabbits that underwent thigh tourniquet compressions of 0 mm Hg, 125 mm Hg, and 350 mm Hg to determine how increased pressure influences contractile function beneath and distal to the tourniquet. The authors state that 2 days after tourniquet removal, the quadriceps and the tibialis anterior muscles of rabbits in the tourniquet group experienced significant loss of contractile forces compared to those of the control group. After 3 weeks, quadriceps force returned to 94% of the maximal control force after 125 mm Hg compression but only to 83% of the maximal control force after 350 mm Hg compression. Tibialis anterior force production was 88% of the mean control force after 125 mm Hg compression and 83% of the mean control force after 350 mm Hg compression. The authors conclude that mechanical injury from tourniquet compression plays a major role in neuromuscular dysfunction, and the magnitude of the compression significantly affects the degree of isometric contractile dysfunction in the quadriceps and tibialis anterior muscles after tourniquet use.
Source: Mohler LR, Pedowitz RA, Lopez MA, et al. Effects of tourniquet
compression on neuromuscular function. *Clin Orthop* 1999 Feb;359:213-20.

Marson BM, Tokish JT. The effect of a tourniquet on intraoperative patellofemoral tracking during total knee arthroplasty. *J Arthroplasty* 1999 Feb;14(2):197-9.

Product Identifier:
(1) Tourniquets; (2) Insall-Burstein II Posterior Stabilized Total Knee Prostheses
Manufacturer: (1) Manufacturer not identified in article; (2) Zimmer Inc [102165], PO Box 708, Warsaw IN 46581-0708
Abstract: The authors investigated whether an inflated tourniquet affected intraoperative patellofemoral tracking during 75 total knee arthroplasties using a posterior stabilized total knee prosthesis. They state that 34 knees tracked properly with or without the tourniquet inflated, 36 knees maltracked with the tourniquet inflated but tracked properly with the tourniquet deflated, and 5 knees maltracked with and without the tourniquet inflated. The authors also state that a lateral release procedure was avoided in patients whose knees tracked incorrectly with tourniquet inflation but tracked correctly without tourniquet inflation. The authors conclude that
use of a tourniquet can alter intraoperative patellofemoral tracking and that the tourniquet should be deflated to more accurately assess tracking before proceeding with lateral release procedures.
Source: Marson BM, Tokish JT. The effect of a tourniquet on intraoperative patellofemoral tracking during total knee arthroplasty. *J Arthroplasty* 1999 Feb;14(2):197-9.

Knüttgen D, Reifenrath W, Autze W, et al. Massive rigor and compartment syndrome after tourniquet in a patient with suspected malignant hyperthermia {letter}. *Acta Anaesthesiol Scand* 1999 Feb;43(2):239-41.

Product Identifier:
Tourniquets
Abstract: The authors report a case of massive rigor and compartment syndrome in the forearm following the removal of a tourniquet from a patient with suspected malignant hyperthermia. The tourniquet was applied at 300 mm Hg during surgery to repair wrist tendons. Immediately following tourniquet removal, the flexor muscles of the forearm turned into a massive rigor, which led to rupture of the previously repaired tendons. A fasciotomy of the region

up to the biceps brachii was required to treat the rigor. The authors state that the combination of malignant hyperthermia and tourniquet was responsible for the muscle rigor and compartment syndrome. The authors conclude that application of a tourniquet can be problematic if malignant hyperthermia has set in.
Source: Knüttgen D, Reifenrath W, Autze W, et al. Massive rigor and compartment syndrome after tourniquet in a patient with suspected malignant hyperthermia {letter}. *Acta Anaesthesiol Scand* 1999 Feb;43(2):239-41.

Wakankar HM, Nicholl JE, Koka R, et al. The tourniquet in total knee arthroplasty. A prospective, randomised study. *J Bone Joint Surg Br* 1999 Jan;81(1):30-3.

Product Identifier:
(1) Tourniquets; (2) Insall-Burstein Mark II Cemented Total Knee Prostheses
Manufacturer: (1) Manufacturer not identified in article; (2) Zimmer Ltd [157058], Dunbeath Rd Elgin Industrial Estate, Swindon Wiltshire SN2 6EA, England
Abstract: The authors describe the effect of a tourniquet in a group of 77 patients undergoing total knee arthroplasty (TKA) with a total knee prosthesis. 37 patients underwent TKA with a tourniquet, while 40 patients underwent TKA without a tourniquet. Bleeding was considered a nuisance in 7 of 40 patients in whom a tourniquet was not used; moderate bleeding was observed in another 6 patients without the tourniquet. 3 of 37 knees in which tourniquets were used exhibited blisters, 1 knee had severe bruising, and 3 knees had oozing wounds, compared to 1 case of blistering, 1 case of severe bruising, and 3 cases of oozing in patients operated on without the tourniquet. The authors state that the tourniquet was not associated with an increased incidence of wound complication or deep vein thrombosis. They state that patients without the tourniquet had better flexion at 1 week postoperatively and that there was no difference at 6 weeks postoperatively. The authors conclude that tourniquet use is safe and effective in patients undergoing TKA with a total knee prosthesis.
Source: Wakankar HM, Nicholl JE, Koka R, et al. The tourniquet in total knee arthroplasty. A prospective, randomised study. *J Bone Joint Surg Br* 1999 Jan;81(1):30-3.

Improper surgical technique and excessive tourniquet time blamed for scarring and radial nerve palsy in arm. *Med Malpract Verdict Settlements* 1998 Sep;15(9):49.

Product Identifier:
Tourniquets
Abstract: A legal case is described in which the plaintiff alleged that the defendant applied excessive inflation time in a tourniquet during arm surgery that resulted in radial nerve palsy and extensive scarring of the left forearm. The defendant claimed that the plaintiff's complications were due to postoperative infection. The case was settled for a confidential amount. (*Tomasa Pena for Christopher Pena, a minor, v. James Hood, M.D., James Schiener, M.D., and Brackenridge Hospital*, Travis County {TX} District Court, Case No. 96-03352.)
Source: Improper surgical technique and excessive tourniquet time blamed for scarring and radial nerve palsy in arm. *Med Malpract Verdict Settlements* 1998 Sep;15(9):49.

Alleged excessive use of tourniquet during thumb surgery blamed for permanent numbness and pain in arm. *Med Malpract Verdict Settlements* 1998 Sep;15(9):51-2.

Product Identifier:
Tourniquets
Abstract: A legal case is described in which a 71-year-old man, the plaintiff, experienced numbness, tingling, and pain in the ulnar nerve region after undergoing joint surgery with the application of a tourniquet for approximately 2 hr. The plaintiff alleged that the defendant doctor applied the tourniquet for an excessive amount of time and caused ulnar neuropathy. The defendant contended that the tourniquet was necessary to provide a bloodless surgical field and that the application time complied with the accepted standard of care. The verdict was in favor of the defense. (*Robert C. Oberlin v. Gregory Hill, M.D.*, Summit County {OH} Court of Common Pleas, Case No. CV1995124350.)
Source: Alleged excessive use of tourniquet during thumb surgery blamed for permanent numbness and pain in arm. *Med Malpract Verdict Settlements* 1998 Sep;15(9):51-2.

Berman AT, Parmet JL, Harding SP, et al. Emboli observed with use of transesophageal echocardiography immediately after tourniquet release during total knee arthroplasty with cement. *J Bone Joint Surg Am* 1998 Mar;80(3):389-96.

Product Identifier:
Pneumatic Tourniquets
Abstract: The authors determined the effect of tourniquet release on hemodynamic stability by imaging the right atrium and the left ventricle of 55 patients during 59 total knee arthroplasties performed with cement and the use of general anesthesia. A tourniquet was applied to the involved limb and inflated to 350 mm Hg. The authors observed showers of echogenic material traversing the right atrium, the right ventricle, and the pulmonary artery in all patients after the tourniquet was deflated, which lasted 3 to 15 min. The mean peak intensity occurred within 30 sec after the tourniquet was released. The mean mixed venous oxygen saturation decreased from 83% ±0.9% before tourniquet inflation to 72% ±1.5%, after tourniquet release, and the mean pulmonary arterial pressure increased from 20 ±1.0 mm Hg before tourniquet inflation to 27 ±1.0 mm Hg after tourniquet release. The pulmonary vascular resistance index increased after release of the tourniquet only in the patients who had echogenic material that was at least 0.5 cm in diameter. Clinical pulmonary embolism developed postoperatively in 3 patients. Blood aspirated from 5 of 10 femoral vein catheters demonstrated fresh venous thrombus. Histological evaluation of the aspirates failed to demonstrate fat, marrow, or particles of polymethyl methacrylate. The authors conclude that the period after release of the tourniquet during total knee arthroplasty with cement represents a critical time of potential hemodynamic instability and that surgeons should consider acute pulmonary embolism when evaluating a patient who has intraoperative hemodynamic collapse during the procedure.
Source: Berman AT, Parmet JL, Harding SP, et al. Emboli observed with use of transesophageal echocardiography immediately after tourniquet release during total knee

arthroplasty with cement. *J Bone Joint Surg Am* 1998 Mar;80(3):389-96.

Improper use of tourniquet during arthroscopic surgery results in palsy and drop foot. *Med Malpract Verdict Settlements* 1997 Oct;13(10):36.

Product Identifier:
Pneumatic Tourniquets
Abstract: A case is reported in which the plaintiff alleged that the defendant did not properly use a pneumatic tourniquet during arthroscopic knee surgery. The plaintiff claimed that the defendant never released the pressure during surgery and that the loss of circulation to the lower limb resulted in palsy and drop foot. The defendant stated that he did release the pressure from the cuff to allow circulation 3 times during the surgery. A defense verdict was returned. (*Christopher Dedrick v. Dr Stephen Bogosian*, Onondaga County {NY} Supreme Court, Case No. 5670/95).
Source: Improper use of tourniquet during arthroscopic surgery results in palsy and drop foot. *Med Malpract Verdict Settlements* 1997 Oct;13(10):36.