AMPUTATION

Original Release/Approval:		1 Mar 2010	Note: This CPG requires an annual review
Reviewed:	Feb 2012	Approved for PACOM:	DEC 2014
☐ Supersedes:	Amputation, 1 Mar 2010	☐	
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1. **Goal.** To provide standardization of care for the performance of wound management and life-saving amputations that will ensure preservation of maximum limb length, promote healing of viable tissues, and facilitate optimal rehabilitative function.

2. **Background**. The notion of the "zone of injury" is dependent upon the mechanism of injury (i.e. blast, gunshot and crush injuries), as well as the co-morbidities and physiologic status of the casualty. Factors such as severe blood loss with massive resuscitation, burns, compartment syndrome, tourniquet use, and contamination load often extend the actual amount of tissue damage beyond that which is apparent on initial visual inspection.[1] Amputation terminology includes *traumatic amputations* which are immediate extremity amputations caused by the wounding mechanism itself. *Primary amputations* are those performed by a surgical team after evaluation of the mangled extremity with the decision not to pursue limb salvage for whatever reason. Secondary amputations can occur early (within 30 days) or late (after 30 days) and are those which occur after some form of limb salvage has been undertaken. Most commonly, primary and secondary amputation are performed for vascular injuries not amenable to repair or resulting in prolonged limb ischemia, nerve injuries not compatible with a functional extremity, or extensive nonviable tissue with potential for uncontrolled sepsis. Current consensus regarding extremity amputation following battle-injury is to preserve limb length and vascularity, facilitate adequate wound drainage, and achieve eventual coverage and closure of the amputation wound.[2]

3. **Evaluation and Treatment.**

   a. Thorough inspection of the wounds with **liberal** use of surgical wound extension is necessary to inspect all levels of tissue including examination of fascial planes. If available, continuous wave Doppler examination and diagnostic arteriography can be used as adjuncts in cases where distal perfusion is a concern.[3]

   b. A meticulous sharp debridement using a scalpel and/or scissors should be a starting point for nearly all wartime penetrating wounds. Removal of all nonviable tissue, including skin, fat, fascia, muscle, and bone, is essential to reduce the load of contamination and necrotic tissue in the wound and is the hallmark of an adequate debridement. The adjunct of irrigation or lavage with normal saline is also important to decrease bacterial count and soiling. This can be accomplished using various devices such as pulse lavage using a battery powered system or gravity irrigation using genitourinary tubing or bulb/syringe. Published clinical data is inconclusive as to which irrigation method is superior (see PACOM JTTS CPG, Initial Management of War Wounds for additional information). Assurance of hemostasis is important prior to evaluation for dressing or closure.[4]

c. In the setting of an extremity amputation, appropriate vascular structures should be ligated proximal to the bone resection but as distal as possible to ensure adequate tissue perfusion. Vascular structures should be separated from nerves prior to ligation.

d. The amputation level should be performed at the most distal level which provides viable bone and soft tissues for later closure. If an amputation is completed, but a fracture exists proximally, consider stabilizing this segment with external fixation, splinting, or pins to preserve length.

e. Be prepared to accept atypical skin and tissue flaps so long as the tissue is viable.

f. ***Do not perform primary closure of amputation wounds. All wounds must be left open.*** Avoid open circular or guillotine amputations if possible. If required, guillotine amputations should be performed at the most distal level with re-evaluation of the open amputation site within the first 24 hours.[5, 6]

4. Post Operative Management.

a. Soft dry dressing should be applied around the amputation site and extremity. Circumferential wraps with gauze rolls and ace wraps must be applied in a figure of eight fashion without excessive compression.

b. The limb may be placed in a splint or bivalve cast to prevent joint contractures and provide soft tissue support when necessary. There should be simple access for wound inspection.

c. In the event of the short skin flaps, skin traction to prevent soft tissue retraction is an option.

d. Avoid placement of pillows under the knee so as to prevent contractures when dealing with amputations below the knee.

e. The negative pressure wound therapy (NPWT) device using reticulated open cell foam (ROCF) material, otherwise known as the Vacuum Assisted Closure (VAC) device, has recently been shown to be an alternate strategy and valuable adjunct in the overall management of amputation wounds.[7] Recent clinical studies support the use of the VAC as a soft tissue wound management adjunct in appropriately prepared wounds as a bridge-to-flap coverage or coverage with a split thickness skin graft. In appropriately debrided and prepared wounds the VAC has been shown to increase the rate of granulation and decrease bacterial colonization leading to effective amputation coverage and or closure.[8] **Use of NPWT/ROCF should be considered only after complete wound debridement and hemostasis have been achieved.** The VAC ROCF sponge should cover the open wound bed and be set to -125 mm Hg continuous pressure.[3] NOTE: Use of VAC dressings has recently been demonstrated to be safe in patients during strategic aeromedical evacuation. The efficacy and long-term sequelae of NPWT/ROCF is not yet fully established but current clinical experience has been largely favorable. Surgeons who elect to employ this wound coverage method as part of their overall wound management strategy should be thoroughly familiar with the VAC system and its correct use.

f. NPWT/ROCF dressings can be left in place for 24 to 48 hours depending upon the extent and acuity of the wound. More extensive and acute soft tissue wounds should have the VAC dressing removed with further irrigation and debridement on shorter intervals

(every 24 hours) compared to less extensive wounds (greater than every 24 hours). Initiation of delayed primary closure from the ends of the wound may be started during these repeat debridements and irrigation with re-application of smaller VAC dressing sponges.

g. Coordinate dressing changes/repeat debridement with evacuation schedule to avoid extended periods without wound care or inspection. Given the extent of many soft tissue wounds dressing changes and repeat debridements should be performed in the operating room affording the patient the comfort of conscious sedation or general anesthesia and the surgeon access to the full array of equipment necessary to perform adequate debridement. Also, reapplication of the VAC dressing may be more complete and effective if performed in the operating room with the support of operating room and anesthesia teams.

5. Performance Improvement (PI) Monitoring.

a. Intent (Expected Outcomes).

1) All amputation wounds are appropriately dressed but NOT primarily closed in theater

b. Performance/Adherence Measures.

1) All amputation wounds were dressed but not closed in theater

c. Data Source.

1) Patient Record

2) DoD Trauma Registry (DoDTR)

d. System Reporting & Frequency.

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

6. Responsibilities. It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

7. References.

[1] *Emergency War Surgery Handbook*, 3rd United States Revision 2004. Borden Institute. Walter Reed Army Medical Center, Washington, D.C. Chapter 22: Soft Tissue Injuries. 2004: 22.1-22.14

[2] Pollak AN. *Use of Negative Pressure Wound Therapy with Reticulated Open Cell Foam for Lower Extremity Trauma*. J Orthop Trauma 2008:

[3] Peck MA, Clouse WD, Cox MW, Bowser AN, Eliason JL, Jenkins DH, Smith DL, Rasmussen TE. *The complete management of extremity vascular injury in a local population: A wartime report from the 332nd Expeditionary Medical Group/Air Force Theater Hospital*, Balad Air Base, Iraq. J Vascular Surgery 2007; 45:1197-1205

[4] Leininger, BE, Rasmussen TE, Smith DL, Jenkins DH, Coppola C. *Experience with wound VAC and delayed primary closure of contaminated soft tissue injuries in Iraq*. J Trauma 2006; 61: 1207-11

[5] Fox CJ, Gillespie DL, O'Donnell SD, Rasmussen TE, Goff JM, Johnson CA, et al. *Contemporary management of wartime vascular injury*. J Vasc Surg 2005;41:638-44

[6] Clouse WD, Rasmussen TE, Peck MA, Eliason JL, Cox MW, Bowser AN, et al. In theater management of vascular injury: two years of the Balad Vascular Registry. J Am Col Surg 2007;204:625-32

[7] Powell ET. *The Role of Negative Pressure Wound Therapy with Reticulated Open Cell Foam in the Treatment of War Wounds*. J Orthop Trauma 2008; 22: S138-S141

[8] Webb, LX, Pape HP. *Current Thought Regarding the Mechanism of Action of Negative Pressure Wound Therapy With Reticulated Open Cell Foam*. J Orthop Trauma 2008; 22: 135-137

Approved by PACOM JTTS Director, JTS Director and PACOM SG

Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Services or DoD.

APPENDIX A

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

1. **Purpose**.

   The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

2. **Background**.

   Unapproved (i.e., "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

3. **Additional Information Regarding Off-Label Uses in CPGs**.

   The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

4. **Additional Procedures**.

   a. Balanced Discussion. Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

   b. Quality Assurance Monitoring. With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

   c. Information to Patients. Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.