JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Vascular Injury (CPG ID: 46)

The CPG provides guidance on the diagnosis, treatment and surgical management of vascular injuries sustained by combat casualties.

Contributors

Col Todd Rasmussen, MC, USAF	CDR Nathaniel Fernandez, MC, USN
CAPT Zsolt Stockinger, MC, USN	MAJ Joseph White, MC, USA
CDR Jared Antevil, MC, USN	LTC Paul White, MC, USA
LTC Christopher White, MC, USA	

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

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BACKGROUND

The treatment of vascular injuries in combat casualties can be a challenging endeavor in a resource limited environment and requires not only technical expertise on the part of the operating surgeon, but solid judgment on when to perform temporizing maneuvers versus definitive repairs. Surgeons at all Role 2 and 3 facilities need to be intimately familiar with the use of vascular shuts as a means to stabilize a critically wounded casualty and then move them along the continuum of care. With the evolution of global conflict, military surgeons at Role 2 facilities may be faced with potential obstacles to timely patient evacuation, or may be tasked to operate in an environment without an available Role 3 facility. They must also therefore be competent in the definitive surgical management of certain common and life or limb-threatening vascular injuries.

EPIDEMIOLOGY OF VASCULAR INJURY

The rate of vascular injury in modern combat is five times that reported in previous wars and one in five (20%) battle injuries (non-return to duty) are classified as hemorrhage control not otherwise specified suggesting the presence of significant bleeding. Using codes for specific blood vessel injuries or repairs, the rate of vascular injury is 12% in OIF and OEF, which is higher than the 1-3% reported in WWII, Korea and Vietnam.[1] Extremity vessels account for 70-80% of vascular injuries while 10-15% are in the cervical region and 5-10% in the torso.[1-3] The widespread training and use of tourniquets in the modern battle field is likely one of the major reasons for the increase in vascular injuries seen. Casualties that would have died in the field in prior conflicts are now reaching medical care.

ECHELONS OF CARE AND VASCULAR INJURY

Each echelon has unique approaches to the management of vascular injury: [3]

- **Role 1** – Hemorrhage control (direct pressure, tourniquet or topical hemostatic agent) or other life-saving interventions and initiation of evacuation.

- **Role 2** – Operations at forward operating locations are abbreviated (<1 hour), however intervention on extremity vascular injury is important and may make the difference in meaningful limb salvage. Primary amputation or ligation is also an acceptable damage control technique when other life-threatening injuries are present or the patient is in extremis. However if limb salvage is to be attempted, initiation of basic maneuvers including removal of tourniquet, exploration and control of the vascular injury, removal of clot (thrombectomy) and administration of heparinized saline through the inflow and outflow vessels are recommended. Restoration of flow can then be established using a temporary vascular shunt followed by fasciotomy and initiation of medical evacuation. Temporary shunt placement for the initial management of proximal extremity vascular injury is associated with very high rates of successful limb salvage, and consistent shunt patency has been demonstrated for periods up to 12 hours.[4,5] However, experience with shunt utilization without systemic anticoagulation for more protracted periods is limited, and the risk of shunt thrombosis is markedly increased when used beyond 12 hours.[6,7] If a significant delay before definitive vascular management is anticipated, Role 2 surgeons should consider definitive management of the injury with repair/reconstruction or ligation, depending on the patient's stability and the experience level of the surgeon.

- **Role 3** – Removal of tourniquet(s) and any temporary vascular shunts placed at forward locations followed by definitive vascular repair using saphenous vein should be performed at this echelon. Synthetic PTFE conduit can be used in the absence of appropriate autologous vein. During aeromedical evacuation the extremity will be difficult to examine, therefore Role 3 surgeons must assure adequacy of limb perfusion, fasciotomy and wound debridement. Primary amputation or ligation is also an

acceptable damage control technique at this echelon of care when other life-threatening injuries are present or the patient is in extremis.

- **Overseas Role 4** – Surveillance of vascular repair including a close assessment of soft tissue wounds and adequacy of tissue coverage in the operating room prior to continuing MEDEVAC.

- **Continental United States (CONUS) Role 5**– Surveillance of vascular repair with duplex or CTA8 as well as assessment of soft tissue wounds and adequacy of tissue coverage is performed at this echelon. Angiography has particular utility in the identification of more subtle vascular injuries (e.g., traumatic pseudoaneurysm, arteriovenous fistula) following blast injury.[9] In some instances, revision of at-risk repairs identified as having a stenosis or inadequate tissue coverage leaving them prone to infection and blowout is necessary.[10] Finally, delayed revascularization of viable but poorly perfused extremities in which ligation was chosen as the initial method of management can be accomplished at this echelon.

DIAGNOSIS OF VASCULAR INJURY

1. **Hard signs such as hemorrhage, obvious ischemia, palpable thrill or expanding** hematoma require immediate management in the operating room, generally with exploration of the injury site with wide exposure to enable vascular control. Ischemia in this situation is defined as the absence of Doppler signal in the extremity on multiple attempts over time, including after initiation of resuscitation and warming. When hard signs of injury are present, there is limited need for other diagnostic tests (i.e. CTA or angiography) which take extra time and may provide findings which cloud decision making.[3,11,12]

2. **Soft signs such as history of significant hemorrhage, injury proximity to major vessels (fracture pattern, dislocation, penetrating wound or blast injury), bruising or hematoma** or question regarding the presence or absence of a palpable pulse require another diagnostic test. This additional test is commonly the continuous wave Doppler with calculation of the injured extremity index for traumatized limbs if possible and CTA or angiography for questionable torso and/or extremity vascular injuries where available.

3. **The injured extremity index** is similar to the ankle-brachial index and is calculated using a manual blood pressure cuff and a continuous wave Doppler. The first step is to determine the pressure at which the arterial Doppler signal returns in the injured extremity as the cuff is deflated, this is the numerator in the equation. Next the cuff and Doppler are moved to the uninjured extremity, ideally an uninjured upper extremity, and again the pressure at which the arterial Doppler signal returns as the cuff is deflated is recorded as the denominator in the ratio. An injured extremity index greater than 0.90 is normal and has a high specificity for excluding major extremity vascular injury.[13]

4. **Angiography has limited utility in the diagnosis of wartime extremity vascular injury** which is, in part, related to the availability and quality of imaging technology in austere environments. Additionally, extremity vasoconstriction associated with shock and hypothermia in the young injured patient may lead to confusing or false positive findings on angiography. Angiography has its greatest utility in the setting of multiple penetrating wounds at various levels of the same extremity and when performed should be done via a cut down on the femoral artery using a 19-21 gauge butterfly needle to inject contrast. In most instances it is acceptable to forego angiography and use an incision to expose the segment in question with the plan to ligate, shunt or repair the vascular injury.

5. **Computed Tomography-Angiography (CTA)** is increasingly available in a mature theater of war and has its greatest utility in the diagnosis and triage of torso and neck wounds. Reports of CTA for evaluation of extremity vascular injury now exist; however this modality should be viewed as an adjunct, as its full utility has yet to be determined. Specifically, CTA for head and neck wounds demonstrates a sensitivity

of 80%.[14,15] Furthermore, this modality takes additional time, IV contrast and technical experience in order to provide accurate and meaningful images.

GENERAL PRINCIPLES OF VASCULAR INJURY MANAGEMENT

Most deploying non-vascular or non-cardiothoracic surgeons will have limited recent experience in vascular surgery. Prior to deployment, training for surgeons should emphasize the basic principles of vascular trauma management, including adequate exposure, proximal and distal control, vessel debridement to viable tissue, the creation of a tension-free anastomosis, repair or shunt, and adequate coverage with viable tissue. The most challenging aspect in the management of a wartime vascular injury is generally related to vascular exposure. As most of these injuries involve previously normal blood vessels, vessel suturing and shunt placement are usually a relatively straightforward technical exercise. However, in the face of tissue destruction, hematoma, distorted anatomic landmarks, and the potential absence of a palpable pulse, the identification and adequate exposure of a wartime vascular injury can be a challenge for even an experienced surgeon. While the deploying surgeon will find the techniques and "pearls" in Appendix A and Appendix B extremely valuable for pre-deployment review and as a reference during deployment, surgeons should also maximize opportunities to review anatomic exposures in cadaveric, simulation, and video settings prior to deployment. Furthermore, an atlas that covers vascular surgery and exposures should be at the immediate ready for every surgeon on a combat deployment.

PERFORMANCE IMPROVEMENT (PI) MONITORING

INTENT (EXPECTED OUTCOMES)

When limb salvage is attempted at Role 2 facilities, arterial inflow is achieved by shunt or repair and patient is then expeditiously transferred to Role 3 for definitive management.

When fasciotomy is performed, all compartments are completely released through full skin and fascial incisions.

When indicated, fasciotomy is performed at the time of re-vascularization of an ischemic extremity.

PERFORMANCE/ADHERENCE MEASURES

1. All patients undergoing limb salvage at a Role 2 facility have arterial inflow restored prior to expeditious transfer to Role 3.

2. When fasciotomy was performed, there was complete release of all compartments through full skin and fascial incisions.

3. When indicated in patients with ischemic extremities, fasciotomy was performed at the time of re-vascularization.

DATA SOURCE

- Patient Record
- Department of Defense Trauma Registry (DoDTR)

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 Trauma System (JTS) Director and the JTS Performance Improvement Branch.

RESPONSIBILITIES

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

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APPENDIX A: EXTREMITY VASCULAR INJURY

> ***NOTE:*** *See Algorithm for Extremity Vascular Injury* Figure 1*. Algorithm for Extremity Vascular Injury*

UPPER EXTREMITY

Subclavian Artery

- Recommendations: Repair
- Utility of temporary shunt: Low
- Method/ Conduit: Interposition graft /6-8mm ePTFE or Dacron

Pearls

- Proximal right subclavian is approached through median sternotomy and the proximal left subclavian through a high left anterolateral thoracotomy
- The supraclavicular approach is through the clavicular head of sternocleidomastoid muscle and scalene fat pad with retraction of phrenic nerve and division of the anterior scalene muscle
- Place gentle role under shoulders and extend head away from side of injury

Avoid injury to phrenic nerve, brachial plexus and vertebral arteries. The proximal left subclavian artery is approached using a high (3rd intercostal space) anterolateral thoracotomy and the innominate and proximal right subclavian artery through a median sternotomy and supraclavicular incision. The innominate vein can be ligated and divided to facilitate exposure to the innominate artery. Alternatively, the mid and distal subclavian arteries on both sides can be exposed through a supraclavicular incision or combined supraclavicular/infraclavicular incisions. There is no requirement to obtain proximal vascular control within the surgical field of injury; using separate incisions through non-traumatized tissues can expedite rapid vascular control. When approaching this injury the operator should err on the side of ample proximal exposure and if necessary, can resect the clavicular head. In an unstable patient it is recommended that initial proximal control be obtained via thoracotomy as this will allow for more rapid control than use of the supraclavicular approach. Because of the technical challenges with exposure, the utility of temporary vascular shunts in this injury pattern is limited. Most often interposition graft using 6-8 mm ePTFE or Dacron is required for subclavian artery repair, being mindful of the vertebral artery and the phrenic nerve. If endovascular capability is available, balloon occlusion of the proximal subclavian artery can be a useful adjunct, and repair with a covered stent can be considered. [2,6]

Axillary Artery

- Recommendations: Repair
- Utility of temporary shunt: High
- Method/ Conduit: Interposition graft/ reversed saphenous vein

Pearls

- Supra- and infraclavicular incisions allows proximal control and distal exposure.
- Prep axilla, arm and hand of upper extremity into operative field.
- Avoid brachial plexus which will be deep or lateral to axillary artery.

Control of the proximal axillary artery is best accomplished through a supraclavicular incision, although the artery itself is exposed through an infraclavicular incision extending into the axilla. The infraclavicular exposure includes division of the clavipectoral fascia, and the blunt separation of the fibers of the pectoralis major muscle for entire the length of the wound. The axillary vein is the first structure to be encountered in the axillary sheath. The axillary artery lies superior and deep to the vein, mobilization and caudal retraction of the axillary vein will expose the first segment of the axillary artery. The first segment of the axillary artery is then visible coursing under the pectoralis minor muscle which can be retracted laterally or divided. It is important when exposing the artery to have the arm and hand prepped in the operative field and extended out onto an arm board. Repair of the axillary artery most commonly involves an interposition graft using reversed saphenous vein.

Brachial Artery

- Recommendations: Repair

- Utility of temporary shunt: High

- Method/ Conduit: Interposition graft/ reversed saphenous vein

Pearls

- Medial approach; adjacent to the median nerve in brachial sheath in bicep/triceps groove.

- Elastic artery with redundancy; flex arm slightly for interposition grafts to avoid kinking.

- Depending upon damage to collaterals, distal ligation (below profunda brachial or deep brachial artery) may be tolerated.

The brachial artery with the median nerve rests in the brachial sheath and is exposed through a medial incision in the upper arm in the groove between the bicep and triceps. The median nerve is the most superficial structure encountered upon entering the brachial sheath. The ulnar nerve runs posterior to the artery which is surrounded by paired deep brachial veins. A common anatomic variant is for there to be a high bifurcation of the brachial artery in the upper third of the arm. Repair is most commonly accomplished using a reversed saphenous vein interposition graft. Although it may be possible to ligate the brachial artery below the origin of the deep (profunda) brachial artery and maintain a viable arm and hand, this proposition is based on intact collateral circulation. Unfortunately collaterals from the shoulder and deep brachial artery are often damaged in the setting of penetrating blast wounds and therefore maintenance of flow through the brachial artery with a temporary shunt or vascular repair is advised. Ligation or primary amputation is an acceptable damage control maneuver if there is not time for shunting or the patient is in extremis.

Radial/Ulnar Arteries

- Recommendations: Selective (repair some but not all)

- Utility of temporary shunt: Low

- Method/ Conduit: Ligation or interposition graft/ reversed saphenous vein

Pearls

- The presence of an arterial Doppler signal in the hand obviates the need for artery repair.

- Repair with saphenous vein in instances where the absence of an arterial signal persists.

Most often the hand has a dual arterial supply and therefore can tolerate ligation of either the radial or ulnar artery. As such, repair or reconstruction of an injury at this level is rare. Perfusion to the hand should be assessed with Doppler before and after occlusion or ligation, and if the absence of a signal persists,

reconstruction with reversed saphenous vein should be performed. Given the relative small muscle mass of the hand and the degree of collateral circulation, ligation is most often tolerated understanding that if ischemia persists, evaluation and revascularization can be performed at a CONUS facility days or weeks later.

LOWER EXTREMITY

Common Femoral Artery

- Recommendations: Repair

- Utility of temporary shunt: High

- Method/ Conduit: Interposition graft/ saphenous vein or 6-8mm prosthetic

Pearls

- Expose abdominal wall and artery coursing under inguinal ligament for proximal control.

- External iliac artery can be controlled through proximal groin or low abdominal incision.

- Coverage with tissue (femoral sheath), sartorius muscle or rectus flap.

Injury to the common femoral artery is often fatal as hemorrhage control in the field is difficult. Exposure is obtained through a single longitudinal incision above the artery (2-3 cm lateral to the pubic tubercle) exposing the artery at the inguinal ligament. A key point in exposing the femoral artery is placing the incision proximal enough so that the abdominal wall and inguinal ligament can be identified first in a consistent and familiar location. Alternatively, proximal control can be obtained in the retroperitoneum (i.e. external iliac) through the proximal extension of this groin incision or by using a limited transverse incision in the lower abdomen. After a transverse-oblique skin incision, the external and internal oblique aponeuroses are divided and the lateral fibers of the internal oblique separated. The transversus muscle and transversalis fascia are opened allowing entrance into the retroperitoneum, and the peritoneum is reflected cephalad, exposing the internal iliac vessels along the medial border of the psoas muscle. Common femoral artery injuries are most commonly reconstructed using reversed saphenous vein, although e-PTFE or Dacron can be used if there is too great of a size mismatch. Placement of a prosthetic graft is acceptable if there is minimal to no contamination and there is adequate coverage, at a Role 2 facility placing a shunt prior to transfer to a higher level of care is preferable to reconstruction with a prosthetic graft. Every attempt should be made to maintain flow into the profunda femoris artery, although the feasibility of this will depend upon the pattern of injury and the comfort level the surgeon to perform a more complicated reconstruction. Coverage of vascular reconstructions in the groin is challenging and the focus of Role 3-4 care and may consist of local viable tissue, the sartorius muscle or other options such as a rectus abdominis transfer flap. [2,17]

Profunda Femorus Artery

- Recommendations: Repair if possible

- Utility of temporary shunt: Low

- Method/ Conduit: Ligation or interposition graft/ saphenous vein

Pearls

- Exposure of proximal profunda is the same (distal extension) of the common femoral.

- If superficial femoral artery is injured, repair of profunda is necessary to heal amputations.

- If superficial femoral is patent, ligation of mid to distal profunda injury is acceptable.

Exposure of the proximal profunda femoris artery is obtained through a longitudinal incision used to expose the common femoral artery. Mid- and distal segments are exposed through a vertical incision made parallel to the lateral border of the Sartorius muscle more lateral incision on the upper thigh, lateral to the proximal sartorius muscle. The sartorius is retracted medially and the rectus femoris is retracted laterally to expose the mid- and distal segments. Proximal profunda injuries should be repaired with reversed saphenous vein interposition graft. This is especially important if there is question about the integrity of the superficial femoral or popliteal vessels. In this setting flow through the profunda is most important to allow healing of subsequent lower extremity amputations. If patency of the superficial femoral artery can be confirmed, ligation of mid and distal profunda femoris injuries is acceptable as they lie deep in the thigh musculature and are not required for leg viability. [17]

Superficial Femoral Artery

- Recommendations: Repair

- Utility of temporary shunt: High

- Method/ Conduit: Interposition graft/ reversed saphenous vein

Pearls

- Medial incision with "bump" under calf, surgeon seated, OR lights over shoulder.

- Exposure of the proximal 1/3 posterior to the sartorius and distal 1/3 anterior to the Sartorius.

- Be wary of adjacent vein and geniculate branches of distal superficial femoral artery (Hunter's canal).

Exposure is performed through a medial thigh incision and the adductors of the leg (i.e. adductor magnus). Exposure is facilitated by placing a lift or "bump" below the knee which allows the femoral artery, sartorius and adductors to be suspended improving separation. Entry into the fascia of the lower thigh (distal superficial femoral artery) should be performed at the upper anterior margin of the sartorius which should be reflected down or posteriorly. Exposure is facilitated with the surgeon seated looking across to the dissection field with lights positioned directly over his or her shoulder if they do not have a headlight available.

When exposing the superficial femoral artery, it is important to recognize the femoral vein which is in close proximity, if not adherent, to the artery. At the distal extent of the artery as it exits the adductor (Hunter's) canal, there are large geniculate side branches which should be preserved or at least not injured which causes hemorrhage. Repair of superficial femoral artery injury is best performed by reversed saphenous vein interposition graft from the uninjured leg.[17]

Popliteal Artery

- Recommendations: Repair

- Utility of temporary shunt: High

- Method/ Conduit: Reversed saphenous vein

Pearls

- Medial incision with "bump" under calf for above knee and under thigh for below knee.

- Henley popliteal retractor with removable, varied depth side blades is valuable.

- Distal exposure by division of gastrocnemius and soleus from tibia allowing dissection to anterior tibial origin (coursing away from dissection plane) and tibial-peroneal trunk.

Vascular injuries in the popliteal space are exposed through a medial incision with the surgeon seated and lights over his or her shoulder. The dissection is extended from above to below the knee and is facilitated by a lift or "bump" under the calf of the leg with the knee flexed. When exposing below the knee, this bump is placed under the thigh. Natural dissection planes exist in exposing the above knee popliteal artery (i.e. popliteal space) with the exception of the need to divide the fibers of the adductor magnus which envelop the distal superficial femoral artery (Hunter's canal). Similarly, a natural dissection plane exists into the popliteal space from below the knee, but added exposure should be accomplished by division of the gastrocnemius and soleus muscle fibers from the medial tibial condyle to allow a lengthy exposure of the below knee popliteal artery to the takeoff of the anterior tibial artery and the tibial-peroneal trunk. To completely expose the popliteal space, the medial attachments of the sartorius, semitendinosis, semimembrinosis and gracilis to the medial condyle of the tibia can be divided. When feasible, the pes anserinus should be reconstructed given its significant role in medial knee stabilization. Weitlaner, cerebellar retractors, flexible Adson- Beckman or Henly popliteal retractors with detachable side blades are necessary to expose the popliteal space. Typically the medial head of the gastrocnemius can be retracted down using one of these devices and does not need to be divided. [17]

Tibial Arteries

- Recommendations: Selective repair (i.e., some but not all)

- Utility of temporary shunt: Moderate

- Method/ Conduit: Ligation or interposition graft with saphenous vein

Pearls

- If a Doppler signal is present at the ankle, there is no need for additional tests or repair

- Doppler exam should be repeated as patient is resuscitated and warmed

- Repair with vein if three tibial arteries injured and an absence of a Doppler signal persists

- As long as there is at least one of the three tibial vessels intact, injuries to one or even two of the tibial vessels can safely be managed by ligation.

The recommended approach to tibial artery injury is one of selective repair (i.e. repair some but not all). Because of their distal location and redundant nature, isolated and sometimes multiple tibial artery injuries are able to be ligated without adverse outcomes. As long as one tibial artery is uninjured and patent to the ankle (i.e. an arterial signal at the ankle or foot), no additional tests or repair is required (especially at Roles 1-3). Continuous wave Doppler exam of the foot is critical in the setting of tibial artery injuries and concern for viability of the foot (i.e. patency of the remaining tibial vessel(s)). Doppler should be repeated over the first hours after injury, especially if the patient presents in shock or cold. Because of the capacity for vasoconstriction, what may initially appear as an ischemic foot from tibial vascular injury may improve with warming and resuscitation (i.e. return of arterial signal). If a signal does not return and there is concern for, or observation of, multiple tibial artery injuries, flow to the foot should be restored using a temporary shunt or interposition graft using saphenous vein.

This selective approach to tibial repair has been shown to be effective, confirming, that although tibial injuries can be ligated, there is a distinct injury pattern which requires repair. Temporary shunts may be placed in tibial vessels although success (patency) is lower than that in larger, more proximal vessels.

The anterior tibial artery is exposed through an anterolateral longitudinal incision midway between the tibia and fibula. The fascia along the lateral border of the anterior tibialis muscle is divided and the plane between the anterior tibialis and extensor digitorum longus muscles is developed. The anterior tibial artery lies along the interosseous membrane.

Exposure of the posterior tibial artery in the deep compartment of the leg is through a medial incision with a lift or "bump" under the knee or thigh. A longitudinal incision is made 2 cm posterior to the posterior margin of the tibia. Division of the tibial attachments of the soleus muscle in the proximal and mid-leg and posterior retraction of the soleus exposes the artery. Reconstruction of a peroneal artery injury is rarely required and ligation is adequate. Importantly, tibial reconstruction is technically more challenging because of the smaller size of the vessels and may therefore take longer to complete. Like other vascular repairs, tibial reconstruction should not be undertaken if the patient has other life threatening injuries or is in extremis. [18]

Extremity Venous Injury

- Recommendations: Selective repair (i.e. some but not all)

- Utility of temporary shunt: Moderate

- Method/ Conduit: Ligation, repair or saphenous interposition graft
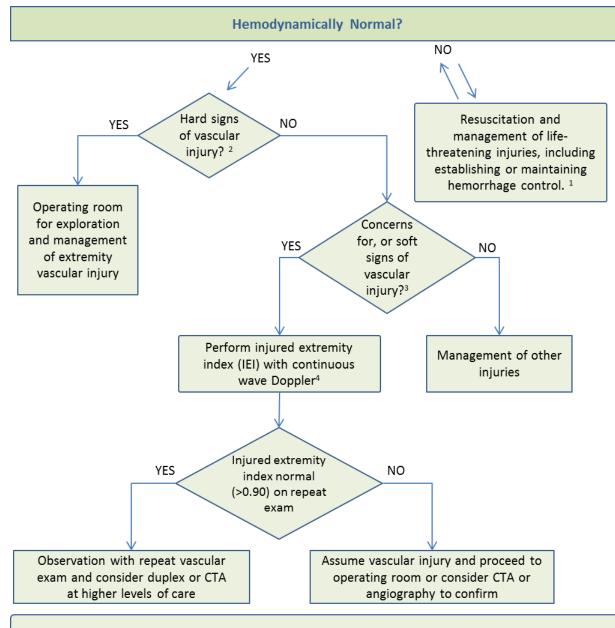
Pearls

- Repair of proximal veins is indicated to reduce venous hypertension and congestion.

- Shunts in proximal veins will remain patent until formal repair can be performed.

- Pneumatic compression device on distal extremity to augment venous flow after repair.

Many extremity venous injuries, especially small, distal veins, can be ligated with no adverse effects because of collateral venous drainage. However, ligation of more proximal or watershed veins, or even axial veins when collaterals have been destroyed by soft tissue wounds, will result in venous hypertension and congestion. In such instances an attempt should be made to repair the vein and restore venous outflow. Temporary shunts have been shown to be effective in restoring venous outflow in the femoral veins until formal repair can be accomplished. Techniques of lateral venorrhaphy are acceptable, although an interposition graft using saphenous vein from the uninjured limb is often necessary.

The patency of vein repairs in the lower extremity is 80% at 24 months with no increased incidence of pulmonary emboli compared to ligation. Additionally, a limb salvage benefit of vein repair compared to ligation has been shown 2 years after injury.[19,20] Despite these advantages, repair of extremity venous injury should only be considered in instances when the patient's overall status is able to tolerate additional operating; otherwise venous ligation is preferred, accepting the increase in morbidity.

Technical considerations include removing thrombus from the distal venous segments with compression (e.g. ace wrap or Esmark bandage) prior to repair. Additionally, following venous repair, placement of a pneumatic compression device distal on the extremity will augment venous flow and improve patency. Lastly, if there is no contraindication, a prophylactic dose of low-molecular weight heparin should be initiated. [19]

Figure 1. Algorithm for Extremity Vascular Injury

Hemodynamically Normal?

YES → **Hard signs of vascular injury?** [2]

NO → Resuscitation and management of life-threatening injuries, including establishing or maintaining hemorrhage control. [1]

- **YES** → Operating room for exploration and management of extremity vascular injury
- **NO** → **Concerns for, or soft signs of vascular injury?** [3]

Concerns for, or soft signs of vascular injury? [3]
- **YES** → Perform injured extremity index (IEI) with continuous wave Doppler [4]
- **NO** → Management of other injuries

Perform injured extremity index (IEI) with continuous wave Doppler [4] → **Injured extremity index normal (>0.90) on repeat exam**
- **YES** → Observation with repeat vascular exam and consider duplex or CTA at higher levels of care
- **NO** → Assume vascular injury and proceed to operating room or consider CTA or angiography to confirm

1. Do not release tourniquets or begin vascular injury exploration if patient is in shock from associated injuries
2. Hard signs: hemorrhage, expanding hematoma, absence of Doppler signal on repeated exam, audible bruit, palpable thrill
3. Soft signs: proximity to major vessel, fracture or dislocation patterns, diminished pulse, report of hemorrhage or shock
4. IEI is occlusion pressure of arterial Doppler signal on injured extremity divided by occlusion pressure of normal limb
   - Normal is > 0.90
   - Repeat Doppler exam and IEI during first hours after injury, especially if patient is cold and hypotensive

APPENDIX B: TORSO VASCULAR INJURY

Thoracic Aorta

- Recommendations: Selective repair
- Utility of temporary shunt: None, except in extremis
- Method/ Conduit: Observation and medical optimization or Dacron graft replacement

Pearls

- If a stable blunt injury, MEDEVAC to Role 3 for possible repair versus MEDEVAC to Role 4.
- Permissive hypotension or B-blocker may decrease risk of rupture
- If hemorrhage from penetrating wounds, entry through left 3rd or 4th interspace, one lung ventilation and rib removal to facilitate exposure of the proximal descending aorta

Management of penetrating injury to the thoracic aorta is very rare given the pre-hospital lethality of this injury. If present, management of thoracic hemorrhage in the setting of penetrating trauma is directed by chest tube location and output (i.e. the hemithorax which is bleeding from tube thoracostomy is the one which is opened). The descending thoracic aorta is approached through the left chest and when injured is surrounded by hematoma. An initial left thoracotomy can be extended into the right chest to approach the thoracic aorta by extending across the sternum ("clam shell" thoracotomy). Aortic control proximal and distal to the hematoma must be obtained including isolation or control of any intercostal arteries in this segment. Aortic clamps are used to arrest flow in this segment and the hematoma is entered with debridement of the injured aorta using scissors. An adequate length of aorta must be debrided to allow placement of large caliber (20-26mm) Dacron graft sewn end-to-end to the proximal and distal segments.

Management of blunt injury to the thoracic aorta (partial transection or pseudoaneurysm) which has reached a temporary stable equilibrium is more common. In this setting and in the absence of hemorrhage from chest tubes, contrast CT imaging is indicated to characterize the injury. Permissive hypotension and selective use of B-blockers is indicated to decrease the risk of aortic rupture during this period. If CT confirms blunt aortic injury, options include early open repair or MEDEVAC. In a patient at Role 1 or 2 with a suspected blunt aortic injury who has normal and stable vital signs and no signs of active hemorrhage from the thorax, MEDEVAC to the Role 3 should occur. At this location the decision will be made regarding options for open or endovascular repair or medical optimization and CCATT transport out of theater. Recent advances in in-theater endovascular capability have made endovascular repair of such injuries possible at certain Role 3 facilities.

Abdominal Aorta

- Recommendations: Repair
- Utility of temporary shunt: Low
- Method/ Conduit: Interposition graft / Dacron

Pearls

- Supraceliac aortic control requires high midline incision along xyphoid, spreading and suspension of rib cage with retractors and nasogastric tube in the esophagus.
- Approach supra-mesocolic Zone I hematomas with left medial visceral rotation (Mattox maneuver).
- Approach infra-mesocolic Zone I hematomas with right medial visceral rotation (Catell-Brash maneuver).

▪ Keep in mind that supra-mesocolic Zone I hematomas may contain transected pancreas.

Blunt and penetrating injuries to the abdominal aorta present as a central (zone I) hematoma with blood in the abdomen at laparotomy. Zone I hematomas should be considered in two locations, supra- or infra-mesocolic, and should be entered once proximal and distal control is established and blood and access are available for transfusion. Supra-mesocolic, Zone I hematomas are best approached by left medial visceral rotation (i.e. Mattox maneuver) which exposes the supraceliac, paravisceral and infrarenal segments of aorta. Infra-mesocolic Zone I hematomas should be approached with the Catell-Brash maneuver exposing the infrarenal aorta and inferior vena cava up to and behind the liver. Proximal aortic control is obtained through the gastrohepatic ligament by retracting the esophagus to the left and dividing the crus. Alternatively the Mattox maneuver exposes the supraceliac aorta from the lateral position, enabling proximal control as well. The iliac vessels or distal aorta can next be controlled, providing isolation before entering the hematoma. Repair techniques for the aorta and its branch vessels range from primary pledgetted closure to replacement with a Dacron interposition graft and depend upon the degree of injury.

Vena Cava

▪ Recommendations: Repair

▪ Utility of temporary shunt: Low

▪ Method/ Conduit: Lateral repair, patch angioplasty or interposition graft / ePTFE

Pearls

▪ Establish resuscitation lines above the diaphragm for abdominal vena cava injuries.

▪ Vena cava injuries should be exposed using the Catell-Brash and Kocher maneuvers.

▪ Lateral repair is acceptable provided that no more than 1/3rd of the lumen is compromised.

▪ If occlusion of the cava results in hypotension, clamp the aorta to support central perfusion.

▪ Retrohepatic, retroperitoneal hematomas should not be disturbed if not actively bleeding.

▪ Several specific strategies applicable to repair of the injured vena cava are listed in the Large Vein Injuries section (section VII).

The approach to the vena cava in the abdomen should be performed using the Cattell-Braasch and Kocher maneuvers exposing the cava, renal veins and the beginning portion of retrohepatic segment. Mobilization of the liver is required to expose the retro-hepatic vena cava; however retrohepatic hematomas should not be disturbed if there is no active bleeding.

Attempts should be made to identify large lumbar veins feeding into the injured segment which may bleed as much as the main channel of the vena cava if not controlled. Because repair of the vena cava is likely to require intermittent occlusion (i.e. sponge sticks or vascular clamps) or ligation in extreme cases, central venous access should be established above the diaphragm (i.e. subclavian or jugular veins) to allow effective volume resuscitation. If compressing or occluding the vena cava results in significant hypotension, the adjacent abdominal aorta may be temporarily occluded to support central pressures while resuscitation takes place. Repair of tangential injuries to the cava can be accomplished using lateral suture repair (i.e. running venorrhaphy) provided that the lumen is not narrowed more than ½ of its native diameter. If lateral repair results in significant narrowing, there is a higher risk of thrombosis leading to pulmonary emboli and anticoagulation should be initiated postoperatively if possible. In instances where lateral repair will result in more than 50% narrowing, patch angioplasty or resection and interposition graft using ePTFE is preferable. Ligation of the infrarenal cava is acceptable as a damage control maneuver, although this carries a significant mortality risk and major morbidity in the form of decreased cardiac preload and significant lower extremity edema. If infrarenal ligation is needed, it should always be accompanied by bilateral lower leg fasciotomies to

reduce the risk for compartment syndrome. Suprarenal occlusion of the IVC is generally not compatible with survival and should be considered a measure of last resort.24

Portal Vein and Hepatic Artery

- Recommendations: Repair

- Utility of temporary shunt: Low

- Method/ Conduit: Primary repair, patch angioplasty, interposition graft / ePTFE or Dacron or saphenous vein

Pearls

- Access to gastrohepatic ligament by Pringle maneuver should precede exploration of the porta hepatis.

- Ligation of hepatic artery injuries is acceptable if the portal vein is patent.

- Lateral venorrhaphy is preferred; ligation of portal vein results in massive bowel edema and systemic hypovolemia.

- Several specific strategies applicable to repair of the injured portal vein are listed in the Large Vein Injuries section (section VII).

Portal vein and hepatic artery injuries typically present as hematomas of the porta hepatis and should be explored after isolation of the gastrohepatic ligament and application of a Pringle maneuver. Next, careful dissection of the porta is performed to determine which structures have been injured. Injuries to the hepatic artery may be repaired with lateral suture placement if limited in severity; ligation of the hepatic artery is acceptable if the portal vein is uninjured. Repair of the portal vein should be attempted using the technique of lateral venorrhaphy if possible. If a large segment of the portal vein is damaged, vein patch angioplasty, or in rare instances, interposition vein graft may be performed. Ligation of the portal vein is an option of last resort and will result in hepatic ischemia and splanchnic congestion and hypervolemia for several days. Importantly, if the capabilities are available then imaging of the biliary system should be considered for associated injuries of the common bile duct and can be performed with cholangiography through the gall bladder.

Mesenteric Arteries

- Recommendations: Repair

- Utility of temporary shunt: Low

- Method/ Conduit: Primary repair, patch angioplasty, interposition graft / ePTFE or Dacron or saphenous vein

Pearls

- Present as supra-mesocolic Zone I hematoma.

- Repair proximal mesenteric artery and vein injuries including portal vein.

- Ligation can be performed for distal artery and vein injuries or as damage control.

Upon entering a supra-mesocolic Zone I hematoma, one may find injury to the mesenteric vessels (artery or vein). Under most circumstances, repair of the proximal superior mesenteric artery and vein, including the portal vein, is indicated using the techniques of primary pledgetted repair, vein patch angioplasty or replacement of the injured segment with interposition saphenous vein graft. The specific type of repair will depend on the location and extent of vessel injury. In cases where injury to the artery or vein is distal (i.e. beyond the middle colic artery or jejunal vein branches) or in which the patient's physiology is severely compromised, the vessels can be ligated.

Renal Arteries

- Recommendations: Selective repair

- Utility of temporary shunt: Low

- Method/ Conduit: Primary repair or patch angioplasty/Dacron or vein

Pearls

- Explore Zone II hematomas from penetrating injury.

- Establish status of contralateral kidney by contrast study or manual palpation.

- Priority is "save-life," and early nephrectomy is required with complex injuries.

- With a renal warm ischemic time > 30-60 minutes, complex repairs are not indicated.

Injury to the renal pedicle (blunt or penetrating) is closely associated with injury to the parenchyma; isolated arterial injury is rare. Essential considerations in the management of renal artery injury in wartime are the warm ischemic time of 30-60 minutes and complexity of renal artery repair. Both of these limit what the surgeon can accomplish in the context of renal artery injury other than ligation and nephrectomy.

If arterial injury manifests as occlusion with renal ischemia, it will be too late to restore flow and function to the kidney by the time the diagnosis is made in the operating room or CT scanner. If the artery is patent and bleeding, an associated Zone II or lateral hematoma requiring exploration will be present and attempts to stop hemorrhage and repair are indicated. These maneuvers may include pledgetted primary repair of the renal artery, patch angioplasty or very rarely interposition graft replacement (aorto-renal bypass). Again, considering the warm ischemic time of the kidney, complex operations to maintain or reestablish perfusion in the renal artery are not recommended and should be abandoned in favor of nephrectomy in most cases.

The method by which to approach an expanding or penetrating zone II hematoma is controversial and case specific. Isolation of the renal pedicle before exploring the hematoma is doctrine in many institutions and has the advantage of aortic isolation and definitive proximal control. However from a practical standpoint, mobilization of the damaged kidney from a lateral to medial direction without hilar control may be faster depending upon the appearance of the injury. The lateral to medial approach is similar to the medial visceral rotation performed for zone I injuries.

Iliac Arteries

- Recommendations: Repair

- Utility of temporary shunt: High

- Method/ Conduit: Interposition graft/ ePTFE or Dacron or saphenous

Pearls

- Explore Zone III hematoma from penetrating wound after establishing aortic control above the hematoma.

- Distal control is obtained at the inguinal ligament (i.e. external iliac arteries).

- Wylie hypogastric (internal iliac) clamps facilitate low-profile control of iliac arteries.

Iliac artery injuries generally present as a Zone III or pelvic hematoma with or without extremity ischemia (check femoral pulses). Exploration of the hematoma should be performed after proximal control is obtained at the infrarenal aorta and the contralateral iliac artery if possible. The distal external iliac artery should be found as it exits the pelvis at the inguinal ligament at a point where it is free from the hematoma. The internal iliac artery

may not be initially controlled or visualized before exploring the hematoma, which often requires opening to expose the internal iliac. The inability to initially control all bleeding from the hematoma necessitates preparation including multiple suction devices, Fogarty occlusion balloons (if available) direct tamponade strategies or devices and alerting anesthesia regarding the need for continued resuscitation during exploration. After proximal and distal control of the common and external iliac arteries is obtained, the hematoma is entered which facilitates exposure and clamping of the internal iliac artery and the injured vessel(s). Common and external artery injuries can be controlled and managed with a temporary vascular shunt if needed or repaired with interposition grafting using saphenous vein or prosthetic conduit (6-8mm ePTFE or Dacron). In an unstable patient or a patient where there is contamination of the field, shunt placement with definitive repair or reconstruction done at a later point is a good option.

If the primary injury is to the internal iliac artery (hypogastric), it may be ligated with 3.0 or 4.0 Prolene on an SH needle. Bleeding from associated iliac veins may be severe and difficult to expose. The iliac artery may be divided if necessary to facilitate exposure of the iliac vein, followed by repair of the artery. At certain Role 3 facilities with endovascular capabilities, selective embolization of bleeding hypogastric artery or branches is an option, particularly in blunt trauma (e.g., pelvic fracture.) The principles which apply to the management of iliac vein injury are discussed in the Management of large vein injuries section.

APPENDIX C: CERVICAL VASCULAR INJURY

Carotid Artery

- Recommendations: Repair.
- Utility of temporary shunt: High.
- Method/ Conduit: Vein patch or vein interposition graft.

Pearls

- Zone I cervical injuries best approached with median sternotomy for ample proximal exposure.
- Early control of common carotid with umbilical tape/Rummel or DeBakey clamp.
- 3 Fr Fogarty with 3-way stopcock is useful to occlude internal carotid back bleeding.
- Shunt and augment mean arterial pressure during carotid repair to perfuse brain.

Most carotid injuries result from penetrating wounds and result in hematoma. Indications for operation are bleeding or injury with interrupted flow (i.e. occlusion). When feasible, contrast CT should be performed for neck wounds. CT aids in the triage for urgent operation, improves operative planning and images the brain as a baseline. Although a selective approach to exploration of zone II neck wounds is acceptable, if a carotid injury is identified, the neck should be explored and an attempt made to repair. The exceptions are blunt injury resulting in carotid occlusion greater than 12 hours or a zone III injury not accessible by standard techniques.

Exposure of the carotid artery is through a generous incision coursing anterior to the sternocleidomastoid and facilitated by a roll under the shoulders, extension of the neck and turning of the head away from the injury. The platysma is divided and the sternocleidomastoid muscle reflected posterolaterally. The internal jugular vein is carefully dissected and mobilized laterally, exposing the carotid artery. The carotid is exposed proximal to the hematoma and controlled with an umbilical tape into a Rummel device (i.e. red rubber catheter). In the absence of uncontrolled bleeding, there is no need to tighten the Rummel; but having it in place gives one this option and allows for securing the proximal end of a temporary shunt.

The dissection proceeds distal into the zone of injury. If bleeding is encountered the Rummel may be cinched or a clamp (angled DeBakey) slid proximal to the umbilical tape using it to pull the carotid up into the clamp, thereby avoiding injury to the vagus nerve. Back bleeding from the internal carotid artery is a favorable sign and can be controlled with a small clamp or a (3 Fr) Fogarty inserted into the internal and inflated using a 1cc syringe and 3-way stop-cock to maintain inflation. The external carotid artery is controlled with vessel loops or ligated. If the internal and common carotid arteries are controlled above and below the injury, a temporary shunt can be placed to maintain perfusion while the injury is identified and options considered. First, the shunt should be placed into the internal carotid artery and secured with a vessel loop or small Javid shunt clamp allowing back bleeding through the shunt. To secure the proximal shunt, an angled DeBakey is placed proximal to the umbilical tape and Rummel device. Then in sequence, the shunt is placed in the common carotid through the Rummel which is partially tightened around the shunt. As it is advanced deeper (more proximal) into the common carotid, the DeBakey clamp is slowly opened allowing the shunt to pass while the Rummel is tightened down fully securing the shunt in place. Alternatively the common carotid artery can be controlled with fingers as the shunt is inserted proximal and the Rummel synched down. If available, Javid shunt clamps can be used to occlude the artery around the shunt instead of the Rummel device.

Repair of carotid artery injuries most commonly requires placement of an interposition saphenous vein graft, although primary repair or vein patch angioplasty can be performed for less severe injuries. To perform the interposition graft over the shunt, the proximal end is removed using the DeBakey clamp to again occlude the common carotid proximal to the Rummel. The vein graft is next placed over the shunt (i.e. shunt in the vein graft lumen). The proximal shunt is reinserted into the common carotid and secured with the Rummel using

previously described sequence. After flow is restored in the shunt, the distal vein graft anastomosis is performed using 6-0 Prolene to the edge of the normal internal carotid. Next the proximal anastomosis to the common is started also with 6-0 Prolene. When the anastomosis is nearly completed, the shunt is removed through the remaining anastomotic opening, first removing the proximal from the common carotid and observing back bleeding from the shunt in the internal carotid. Finally the shunt is removed from the internal and the vein graft flushed generously with heparinized saline and the anastomosis completed. Alternatively the reconstruction can be performed without a shunt, however, this exposes the ipsilateral hemisphere to prolonged ischemia. Regardless of whether or not a shunt is used, the mean arterial pressure should be kept above 90mmHg during the repair to optimize cerebral perfusion.

Alternatively the reconstruction can be performed without a shunt, however, this exposes the ipsilateral hemisphere to prolonged ischemia. Regardless of whether or not a shunt is used, the mean arterial pressure should be kept above 90mmHg during the repair to optimize cerebral perfusion. If no other life threatening injuries are present, a small amount (50u/kg) of systemic heparin is recommended along with generous flushing of the repair with heparinized saline to prevent platelet aggregation and clot formation. Ligation of the internal carotid artery is an acceptable damage control maneuver to stop hemorrhage but has an acute stroke rate of 30-50%.

If no other life threatening injuries are present, a small amount (50u/kg) of systemic heparin is recommended along with generous flushing of the repair with heparinized saline to prevent platelet aggregation and clot formation. Ligation of the internal carotid artery is an acceptable damage control maneuver to stop hemorrhage but has an acute stroke rate of 30-50%.

Vertebral Artery

- Recommendations: Ligate
- Utility of temporary shunt: None
- Method/ Conduit: N/A

Pearls

- Bleeding vertebral artery injuries are ligated with no role for reconstruction in theater.
- Vertebral artery occlusions are managed with anticoagulation if it is not contraindicated.
- Endovascular embolization is an option if injury is not accessible by standard exposure.

Repair of vertebral artery injuries in wartime is extremely rare and most commonly bleeding from this vessel is ligated as a matter of necessity during neck exploration. Alternatively, vertebral artery injury (occlusion or extravasation) can be discovered on a contrast CT scan. There should be a high index of suspicion for this injury with cervical spine fractures. In instances of acute vertebral artery occlusion, anticoagulation is recommended to reduce the risk of posterior circulation stroke although the clinical evidence to support this is limited. If associated injuries preclude use of systemic heparin, then antiplatelet therapy should be initiated.

Jugular Vein

- Recommendations: Selective repair
- Utility of temporary shunt: None
- Method/ Conduit: Lateral venorrhaphy, vein patch or saphenous vein

Pearls

- Significant jugular vein injuries can be ligated without adverse effects.
- Repair of jugular injuries should be considered in the setting of TBI with elevated ICP.

Repair instead of ligation of jugular vein injuries may be indicated in instances of associate closed head injury to reduce intracranial pressures, although little data exists to support this practice. Minor jugular vein injuries can be repaired by lateral suture repair (venorrhaphy) while patch angioplasty or interposition vein graft are options for more extensive injuries. Operative exposure of the jugular vein is the same as that described for the carotid artery.

APPENDIX D: MISCELLANEOUS TOPICS

LARGE VEIN INJURIES

Pearls

1. **Formal control (DeBakey clamps) is acceptable** but may be difficult or not advisable as it risks causing injury or may not be needed if injury is limited to the side wall of the vein.

2. **Initial control** can be accomplished by one or more fingers on the bleeding segment.

3. **Organize the operating room and confirm availability of blood and central venous access.**

4. **Venous access** above the heart if operating on injury to the inferior vena cava.

5. **Optimal lighting**, exposure (i.e. extend incisions) and two or more suction devices.

6. **Avoid too small of a needle and suture** which are difficult to maneuver in blood. 4-0 Prolene on an SH tapered needle is substantive suture on a needle large enough to see.

7. **Fingers replaced with a low profile tampanode device** such as a small sponge stick or Wecksorb "K" dissector (i.e. Kitner device) as bleeding is evacuated.

8. **Passes of suture are made** capturing muscle or soft tissue if possible (i.e. pledget-effect). Tie the knot to begin running venorrhaphy or place second pass in "figure-of-8" fashion.

9. **Felt pledgets can be used,** but may not be available.

10. **Hemorrhage control with ligation** is preferable to patency with death from exsanguination.

LIGATION OF VESSELS

Pearls

1. **Acceptable damage control maneuver** especially for small, more distal arteries and veins

2. **Temporary vascular shunting** to restore perfusion should be considered before ligation

3. **Continuous wave Doppler** should be checked before ligation to judge perfusion/viability

Ligation of vascular injuries was the mainstay of treatment for centuries and should not be overlooked as a damage control option; especially at Role 2 facilities where operations are best abbreviated (≤ 1 hr). This technique is especially useful in small distal vessels (tibial, forearm and arm below the take-off of the profunda brachial artery) when patients are in extremis. Use of temporary vascular shunts or even repair should be considered before ligation, however, if not available or feasible ligation should be completed. Continuous wave Doppler may also be useful in assessing perfusion to the extremity distal to the vessel in question.

FOGARTY THROMBECTOMY CATHETERS

Pearls

1. Sized at 2-7 Fr; **maximum balloon diameter** of the 2 and 3 Fr catheters is 4 and 5 mm.

2. **Inflate with saline** using 1cc tuberculin syringe (0.2-0.75cc) while withdrawing from vessel.

3. **Goal is clot, not intima,** removal so don't over-inflate or "drag" too much.

4. **May be used to control bleeding** with use of a 3-way stop cock to maintain inflation.

Fogarty catheters are a key tool in the armamentarium of vascular injury management. Used primarily to remove thrombus, they can also be used to arrest bleeding from within the lumen of the vessel. The most common size used in extremity vascular injury is 2 and 3 Fr although the maximum inflated diameter of the 4 Fr Fogarty catheter is 9 mm which can be used for balloon occlusion of the femoral and iliac vessels. At least one pass of a Fogarty should precede extremity vascular injury repair to assure removal of the traumatic thrombus burden before restoring inflow and outflow. The key tenet is not to cause native vessel damage. To lessen the risk of damage, avoid advancing the catheter too distal in the smaller vessels of the leg and arm and avoid over aggressive, static balloon inflation (i.e. angioplasty or "intimectomy"). Using a Fogarty balloon to control bleeding from within the vessel lumen requires a 3-way stop cock to maintain inflation once the bleeding has been stopped.

TEMPORARY VASCULAR SHUNTS

Pearls

1. Inline shunts rest in the vessel ("in-situ") while long external shunts are designed to loop.

2. In-line Argyl shunts come in cylinder container with 8, 10, 12 and 14 Fr sizes.

3. In-line Javid shunts are longer and individually packaged.

4. Sundt shunts are designed with short (15cm; inline) and long (30cm; external) profiles.

5. Equal success has been had with Argyl, Javid and Sundt without systemic anticoagulation.

6. Secured with silk ligatures, patent for up to 6 hours; reports of longer duration exist.

7. Shunts should be removed with formal repair in-theater prior to medevac to Role 4.

Temporary vascular shunts are effective and should be considered in the management of nearly all extremity vascular injury patterns including proximal venous injuries. Their main advantage is provision of early restoration of flow and mitigation of the damaging effects of arterial ischemia and venous hypertension. As an abbreviated procedure compared to formal vascular repair, shunting extends the window of opportunity for limb salvage in some patterns of vascular injury. Although the patency at 3-4 hours is higher in larger, more proximal vessels (axillary/brachial and femoral/popliteal), shunts have been used effectively in smaller (distal brachial/forearm and tibial) vessels. Outcomes of extremity vascular injury managed with temporary shunts have been recorded demonstrating no adverse effect of this technique and a limb salvage advantage in the most severely injured limbs (MESS ≥ 8). 2, 5, 20

PEDIATRIC VASCULAR INJURIES

Pearls

1. Intervention should be avoided in those less than 10 years old given propensity for spasm.

2. Ligation is more well tolerated in infants and toddlers given ability to recruit collaterals.

3. Perform interrupted suture lines (6-0 Prolene) to allow expansion with growth of child.

Although rare, deployed surgeons can expect to see young patients with vascular injury. Intervention of any type, including angiography, should be avoided in those less than 5 years even if an extremity appears ischemic (i.e. without Doppler signal). The small size of arteries in children and their propensity for vasospasm makes it more likely that an intervention will do harm or confuse the clinical scenario rather than improve the situation. Because of the ability of children to tolerate relative limb ischemia and to develop collateral circulation, ligation of bleeding vessels alone is recommended with warming of the extremity and resuscitation. In rare cases, in children older than 8, reconstruction of larger proximal arteries can be accomplished using reversed saphenous

vein. In such instances, the anastomosis should be performed using interrupted suture allowing expansion as the child grows. 16

ENDOVASCULAR CAPABILITY & INFERIOR VENA CAVA FILTERS

(See [Trauma-Specific Endovascular Inventory Tables](#)) [14]

Pearls

1. Techniques should be used in a small subset of injuries and directed by a trauma surgeon.

2. Indications for vena cava filter include inability to initiate chemoprophylaxis within 48 hours of injury and the occurrence of pulmonary embolus while on chemoprophylaxis.

The emergence of catheter based, endovascular technology to manage injury in the civilian setting has been expanded to the wartime setting. Although advantageous in a small set of combat injuries, endovascular capability in austere settings is in its early stages and its application should be directed by appropriately trained surgeons or interventional radiologists. Injury patterns and procedures which lend themselves to endovascular techniques include central injuries of the thoracic aorta and brachiocephalic vessels (subclavian and carotid) and select patterns of solid organ and pelvic injury amenable to coil embolization. Placement of vena cava filters to reduce the risk of pulmonary thromboembolic events is indicated in patients who cannot receive chemoprophylaxis or therapy with heparin. A trauma specific endovascular inventory for in-theater capability is listed in [Trauma-Specific Endovascular Inventory Tables](#).

Indications for placement of an inferior vena cava filter include an inability to initiate chemoprophylaxis with low molecular weight heparin within 48 hours of a significant injury and the occurrence of a pulmonary embolus while on chemoprophylaxis. Examples of contraindications to chemoprophylaxis include significant traumatic brain, solid organ or pelvic injuries with bleeding. The Günther-Tulip™ (Cook Medical, Inc.) filter is currently recommended because of its established record of success and it ability to be removed in certain circumstances. (See [Trauma-Specific Endovascular Inventory Tables](#).)

USE OF PROSTHETIC GRAFT MATERIAL

Pearls

1. **ePTFE (Gortex) or Dacron** used for central torso vascular injuries (aorta, great vessels).

2. **Prosthetic conduit acceptable as last resort** in extremities when vein cannot be harvested.

3. **If prosthetic used in extremity injury, notify higher levels of care to facilitate surveillance.**

Prosthetic graft materials such as ePTFE (Gortex) or Dacron should be reserved for open reconstruction of the aorta and large torso vessels and used very rarely as conduit for extremity vascular injury. Wartime experience has demonstrated poor incorporation of prosthetic grafts in extremity wounds and a propensity for infection compared to saphenous vein. Additionally, extrapolation of civilian data suggests improved patency of vascular reconstructions using saphenous vein. In the rare instance (i.e. damage control) when prosthetic conduit is used for extremity vascular injury, communication with higher levels of care should occur so that appropriate surveillance or even removal of the graft and replacement with vein can occur. [2]

HARVESTING & USE OF AUTOLOGOUS VEIN

Pearls

1. Use reversed greater saphenous vein from uninjured extremity.

2. Expose at saphenofemoral junction or anterior to medial maleolus (consistent locations).

3. Be sure to mark anatomically distal end as "in-flow" assuring reversal of vein conduit.

4. Introduce 18 ga. plastic vein or metallic olive tip cannula to distend with heparin saline.

Because of its versatility, resistance to infection, propensity for tissue incorporation and favorable patency rates, saphenous vein for interposition graft or patch material is favored. The greater saphenous vein s may be consistently located at the saphenofemoral junction (2cm medial to the pubic tubercle) or 1-2 cm anterior to the medial malleolus. Identifying the actual saphenofemoral junction is important to confirm that the vein being exposed is truly the main channel saphenous and not an accessory branch or anterior saphenous (i.e. must follow back to main saphenofemoral junction). Nearly always in the setting of trauma the vein appears in-situ as "too small" or "not adequate" due to vasoconstriction or spasm.

Nonetheless, after confirming that the vein being exposed is the main channel saphenous, the specimen should be removed and dilated on the back table with firm infusion of heparin saline using a 14-18 gauge plastic vein cannula or the metallic olive tip cannula. Persistence and this maneuver almost always results in a markedly improved and dilated vein ready to be used for repair. Reversal of the vein must also be confirmed as venous valves will not permit flow in a retrograde fashion.

SOFT TISSUE COVERAGE & ANASTAMOTIC DISRUPTION

Pearls

1. **Cover vascular repairs** with available, viable local tissue (muscle and adipose)

2. If no soft tissue to cover, **route grafts** out of zone of injury.

3. A poorly covered **vascular anastamosis** can "blowout," but not in the early (< 5 day) period.

4. **Avoid direct placement of negative pressure** wound therapy sponge on vascular structures.

Soft tissue coverage of vascular repairs is required to assure incorporation and prevent infection and blowout. Option 1 is to immediately cover the repair with viable local soft tissue (muscle and adipose). The negative pressure wound therapy device (VAC®, Kinetic Concepts Inc.) is useful on top of such coverage as it provides a closed dressing which removes wound effluent and decreases bacterial counts. This wound adjunct has been found to assist with accomplishing delayed primary closure of soft tissue wounds over vascular repairs or coverage with skin grafts. The reticulated open-cell foam sponge of the VAC® should not be placed directly on vessels, however when used over viable tissue covering the vascular repair, VAC® has resulted in excellent outcomes with no increase in graft-related complications or blowouts.

If no tissue is available to cover the vascular repair, one can route an interposition graft out of the zone of injury through another myocutaneous or even subcutaneous path. As a last resort, the vascular reconstruction can be left with marginal coverage at Role 2 and 3 facilities; however in these cases close examination must occur at Role 4 facilities. In these rare instances higher levels of care should pursue transfer of viable tissue from other locations (sartorius, rectus abdominis or other muscle) in order to definitively cover the repair within 5-7 days. Although it is acceptable for Role 2 and 3 providers to leave a graft with uncertain coverage, the onus of care then falls heavily on Role 4 facilities to inspect, cover, re-route or even ligate the graft to reduce the risk of catastrophic blowout.

It is important to recognize that even in the best of civilian and wartime circumstances that there has been historically and remains currently a finite risk of anastomotic disruption. Using the management strategies described above the risk of graft blowout has been within an acceptably low range of 1-2% throughout the wars in Iraq and Afghanistan. 15, 23

ANTICOAGULATION/RECOMBINANT FACTOR VII USE

Pearls

1. **Heparin saline is typically 1000u/liter** although other mixtures with or without papaverine are acceptable; there is no evidence that other 'vein solutions' offer any advantage.

2. **Systemic anticoagulation** is achieved with 50 u/kg of IV heparin with1000 u repeated at 1 hr; repeat doses are not recommended given the propensity for bleeding in wartime injury.

3. **"Regional anticoagulation"** is the use of heparin saline flush in the inflow/outflow vessels.

4. The **use of recombinant factor VII** has been shown not to negatively impact vascular injury repair. However, its remains a legitimate concern in this setting and its use should be limited to instances of refractory, non-surgical bleeding (e.g. coagulopathy of TBI).

TRAUMA-SPECIFIC ENDOVASCULAR INVENTORY TABLES

Table 1. Imaging Systems, Endovascular Accessories, Wires and Sheaths

Imaging systems and hardware	
Description	**Quantity**
General Electric Mobile Fluoroscopic Unit with Vascular Imaging Package (9800 or Greater) **Or** Philips BV Pulsera with Vascular Imaging Package Mobile Fluoroscopy Unit	2 (at Role 3, 2 working fluoroscopy units with vasc package + 1 in storage- this has proven itself)
Medrad Mobile Power Contrast Injection System (not CT Scan Component) Mark V ProVis PPD 110 60 507 with Initial Disposables	1
Zonare Z.ONE Mobile Ultrasound Machine with Peripheral Vascular Imaging Package	1
Mobile Fluoro Table: Steris Surgigraphic 6000 Volts: 100/120/220/230-240 Amps: 5.0/4.2/2.4/2.0 Hz 50/60	1

Accessories			
Company	**Catalog #**	**Description**	**Quantity**
Boston Scientific	44-169	Arterial Entry Needle/18 gauge (box 10)	20
Navilyst	45-994	Mini-Stick/5 Fr/Nitinol w/Plat tip Wire (micro-puncture kit)	20
Boston Scientific	15-105	Inflation Device (Each)	5
Boston Scientific	46-550	Torque Device (box 12)	25
Boston Scientific	15-322	Gateway Y-Adapter (box 10)	20
Navilyst	90510002	Off-line Waste Container+/500 mL capacity	40
Navilyst	70055009	Namic 3-way Stopcock+/Rotating Adaptor, Port on Right/1050 psi	50
Navilyst	91051483	Female to rotating adapter 48" flexCI (1200PSI) high pressure injection tubing	25

Wires			
Company	**Catalog #**	**Description**	**Quantity**
Boston Scientific	46-502	Amplatz Super Stiff™ Wire/.035/260cm/J-tip (box 5)	10
Boston Scientific	46-525	Amplatz Super Stiff™ Wire/.035cm/180 (box 5)	10
Boston Scientific	46-526	Amplatz Super Stiff™ Wire/.035cm/260cm (box 5)	10
Boston Scientific	46-152	Zipwire™/.035/180cm/angled tip (box 5)	10
Boston Scientific	46-154	Zipwire™/.035/260cm/angled tip (box 5)	10
Boston Scientific	49-147	Standard starter wire with Bentson or J-tip/.035/180cm (box 5)	10
Boston Scientific	49-157	Standard Rosen starter wire /.035/260cm (box 5)	10

Sheaths			
Company	**Catalog #**	**Description**	**Quantity**
Starter and Short Sheaths			
Boston Scientific	15-711B	Super Sheath™/5 Fr/11cm	10
Boston Scientific	15-962B	Super Sheath™ RO/6 Fr /11cm	10
Boston Scientific	15-963B	Super Sheath™ RO/7 Fr /11cm	10
Boston Scientific	15-964B	Super Sheath™ RO/8 Fr /11cm	10
Boston Scientific	15-966B	Super SheathC RO/7 Fr /25cm (box 10)	10
Boston Scientific	15-967B	Super Sheath™ RO/8 Fr /25cm (box 10)	10
Boston Scientific	15-969B	Super Sheath™ RO/9 Fr /11cm (box 10)	10
Boston Scientific	15-727B	Super Sheath™ /11 Fr /11cm (box 10)	10
Boston Scientific	15-740B	Super Sheath TM/14 Fr/11 cm (box 10)	10
Boston Scientific	15-739B	Super Sheath TM/14 Fr/25 cm (box 10)	10
Long, Small Diameter Sheaths			
Terumo	RSR01	Destination® Sheath/6 Fr/45cm	5
Terumo	RSC05	Destination® Sheath/6 Fr /90cm	5
Long, Large Diameter Sheaths			
Arrow International	CL-07980	Super ArrowFlex™/9 Fr /80 cm	4
Arrow International	CL-71180	Super ArrowFlex™/11 Fr /80 cm	4
Cook, Inc	G09691	Check-Flo™ G09691 RCFW-16.0P-38-30-RB/16Fr/30cm	4

Table 2. Catheters and Balloons

Company	Catalog #	Description	Quantity
Catheters			
Boston Scientific	31-531	Imager™ II/Contralateral Flush/5/65cm	10
Boston Scientific	31-515	Imager™ II/Pigtail Flush/5Fr/100cm	10
Boston Scientific	31-410	Imager™ II/BERN/5Fr/65cm	10
Boston Scientific	31-405	Imager™ II/BERN/5Fr/100cm	10
Boston Scientific	31-414	Imager™ II/H1/5Fr/100cm	10
Boston Scientific	31-458	Imager TMII/Contra 2/5Fr/65cm	10
Cook Medical	G11209	Beacon Tip Visceral Selective HNBR5.0-38-80-P-NS-VS	10
Terumo Medical	CG505	Glidecath®/5/ST/65cm±	15
Terumo Medical	CG506	Glidecath®/5/ST/100cm±	15
AngioDynamics	12401812	Uni*fuse™ Infusion/Thrombolytic Catheter/5Fr x135cmx10cm infusion lengthΔ	2
AngioDynamics	12401813	Uni*fuse™ Infusion/Thrombolytic Catheter/5Fr x135cmx20cm infusion lengthΔ	2

Company	Catalog #	Description	Quantity
AngioDynamics	12401815	Uni*fuse™ Infusion/Thrombolytic Catheter/5Fr x135cmx40cm lengthΔ	2
Angioplasty and Compliant Occlusion Balloons			
Medtronic, Inc.	REL46	Reliant™ Large diameter (46mm) occlusion balloon* (100cm length, 12 Fr sheath)	2
Boston Scientific	17-566	UltraThin™ SDS/4-40mm/75 cm length delivery+ (5Fr sheath)	2
Boston Scientific	17-568	UltraThin™ SDS/4-40mm/135 cm length delivery+ (5Frsheath)	2
Boston Scientific	17-596	UltraThin™ SDS/5-40mm/75 cm length delivery+ (5Fr sheath)	2
Boston Scientific	17-598	UltraThin™ SDS/5-40mm/135 cm length delivery+ (5Frsheath)	2
Boston Scientific	17-626	UltraThin™ SDS/6-40mm/75 cm length delivery+ (5Fr sheath)	2
Boston Scientific	17-628	UltraThin™ SDS/6-40mm/135 cm length delivery+ (5Frsheath)	2
Boston Scientific	17-656	UltraThin™ SDS/7-40mm/75 cm length delivery+ (6Fr sheath)	2
Boston Scientific	17-658	UltraThin™ SDS/7-40mm/135 cm length delivery+ (6Frsheath)	2
Boston Scientific	17-686	UltraThin™ SDS/8-40mm/75 cm length delivery+ (6Fr sheath)	2
Boston Scientific	17-688	UltraThin™ SDS/8-40mm/135 cm length delivery+ (6Frsheath)	2
Boston Scientific	17-711	UltraThin™ SDS/9-40mm/75 cm length delivery+ (7Fr sheath)	2
Boston Scientific	17-713	UltraThin™ SDS/9-40mm/135 cm length delivery+ (7Frsheath)	2
Boston Scientific	17-736	UltraThin™ SDS/10-40mm/75 cm length delivery+ (7Frsheath)	2
Boston Scientific	17-738	UltraThin™ SDS/10-40mm/75 cm length delivery+ (7Frsheath)	2
Company	**Catalog #**	**Description**	**Quantity**
Catheters			
Boston Scientific	31-531	Imager™ II/Contralateral Flush/5/65cm	10
Boston Scientific	31-515	Imager™ II/Pigtail Flush/5Fr/100cm	10
Boston Scientific	31-410	Imager™ II/BERN/5Fr/65cm	10
Boston Scientific	31-405	Imager™ II/BERN/5Fr/100cm	10
Boston Scientific	31-414	Imager™ II/H1/5Fr/100cm	10
Boston Scientific	31-458	Imager TMII/Contra 2/5Fr/65cm	10
Cook Medical	G11209	Beacon Tip Visceral Selective HNBR5.0-38-80-P-NS-VS	10
Terumo Medical	CG505	Glidecath®/5/ST/65cm±	15
Terumo Medical	CG506	Glidecath®/5/ST/100cm±	15
AngioDynamics	12401812	Uni*fuse™ Infusion/Thrombolytic Catheter/5Fr x135cmx10cm infusion lengthΔ	2
AngioDynamics	12401813	Uni*fuse™ Infusion/Thrombolytic Catheter/5Fr x135cmx20cm infusion lengthΔ	2
AngioDynamics	12401815	Uni*fuse™ Infusion/Thrombolytic Catheter/5Fr x135cmx40cm lengthΔ	2

Angioplasty and Compliant Occlusion Balloons			
Company	Catalog #	Description	Quantity
Medtronic, Inc.	REL46	Reliant^{TM} Large diameter (46mm) occlusion balloon* (100cm length, 12 Fr sheath)	2
Boston Scientific	17-566	UltraThin^{TM} SDS/4-40mm/75 cm length delivery+ (5Fr sheath)	2
Boston Scientific	17-568	UltraThin^{TM} SDS/4-40mm/135 cm length delivery+ (5Frsheath)	2
Boston Scientific	17-596	UltraThin^{TM} SDS/5-40mm/75 cm length delivery+ (5Fr sheath)	2
Boston Scientific	17-598	UltraThin^{TM} SDS/5-40mm/135 cm length delivery+ (5Frsheath)	2
Boston Scientific	17-626	UltraThin^{TM} SDS/6-40mm/75 cm length delivery+ (5Fr sheath)	2
Boston Scientific	17-628	UltraThin^{TM} SDS/6-40mm/135 cm length delivery+ (5Frsheath)	2
Boston Scientific	17-656	UltraThin^{TM} SDS/7-40mm/75 cm length delivery+ (6Fr sheath)	2
Boston Scientific	17-658	UltraThin^{TM} SDS/7-40mm/135 cm length delivery+ (6Frsheath)	2
Boston Scientific	17-686	UltraThin^{TM} SDS/8-40mm/75 cm length delivery+ (6Fr sheath)	2
Boston Scientific	17-688	UltraThin^{TM} SDS/8-40mm/135 cm length delivery+ (6Frsheath)	2
Boston Scientific	17-711	UltraThin^{TM} SDS/9-40mm/75 cm length delivery+ (7Fr sheath)	2
Boston Scientific	17-713	UltraThin^{TM} SDS/9-40mm/135 cm length delivery+ (7Frsheath)	2
Boston Scientific	17-736	UltraThin^{TM} SDS/10-40mm/75 cm length delivery+ (7Frsheath)	2
Boston Scientific	17-738	UltraThin^{TM} SDS/10-40mm/75 cm length delivery+ (7Frsheath)	2

Table 3. Endovascular Stents

Bare Metal, self-expanding			
Company	**Catalog #**	**Description**	**Quantity**
Boston Scientific	38948-6401	Sentinol™ 6x40mmx135 cm length delivery+ (6Fr sheath)	2
Boston Scientific	38948-7401	Sentinol™ 7x40mmx135 cm length delivery+ (6Fr sheath)	2
Boston Scientific	38948-8401	Sentinol™ 8x40mmx135 cm length delivery+ (6Fr sheath)	2
Boston Scientific	38948-1401	Sentinol™ 10x40mmx135 cm length delivery+ (6Fr sheath)	2
Covered, self-expanding endografts and aortic/large vessel endografts			
Company	**Catalog #**	**Description**	**Quantity**
W.L. Gore	VBC050502	Viabahn™ 5x50mmx120 cm length delivery (7Fr sheath)	4
W.L. Gore	VBC060502	Viabahn™ 6x50mmx120 cm length delivery (7 Fr sheath)	4
W.L. Gore	VBC080502	Viabahn™ 8x50mmx120 cm length delivery (8 Fr sheath)	4
W.L. Gore	VBC100502	Viabahn™ 10x50mmx110 cm length delivery (11 Fr sheath)	4

Company	**Catalog #**	**Item#**	**Description**	**Quantity**
Medtronic	TB2222C116X	M708499B001	TALENT Thoracic 22mm	1
Medtronic	TF2424C116X	M708499B001	TALENT Thoracic 24mm	1
Medtronic	TF2828C116X	M708499B001	TALENT Thoracic 28 mm	1

Company	**Catalog #**	**Description**	**Quantity**
Medtronic	IEXC121255	AneuRx AAAdvantage Iliac Limb Ext 12mm	2
Medtronic	IEXC141455	AneuRx AAAdvantage Iliac Limb Ext 14mm	2
Medtronic	IEXC161655	AneuRx AAAdvantage Iliac Limb Ext 16mm	2
Medtronic	IEXC181855	AneuRx AAAdvantage Iliac Limb Ext 18mm	2
Medtronic	AEXC202040	AneuRx AAAdvantage Aortic Cuff Extension 20mm	2
Medtronic	AEXC242440	AneuRx AAAdvantage Aortic Cuff Extension 24mm	2
Medtronic	AEXC282840	AneuRx AAAdvantage Aortic Cuff Extension 26 mm	2

Table 4. IVC Filters and Ancillaries

IVC Filters, retrievable			
Catalog #	**Description**		**Quantity**
Cook, Inc	IGTCFS-65-JUG	Gunther-Tulip/Jugular	5
Cook, Inc	IGTCFS-65-FEM	Gunther-Tulip/Femoral	5
Embolics, Snares, Dilators, Thrombolytics, and Low Osmolarity Contrast			
Coils, Cook Medical			
Catalog #	**Description**		**Quantity**
G10415	Tornado Platinum Coils/.035/5-3mm MWCE-35-5/3-TORNADO		10
G10417	Tornado Platinum Coils/.035/7-3mm MWCE-35-7/3-TORNADO		10
G10413	Tornado Platinum Coils/.035/10-5mm MWCE-35-10/5-TORNADO		10
G26994	Nester Platinum Coils/.035/6mm MWCE-35-14-6-NESTER		10
G26995	Nester Platinum Coils/.035/8mm MWCE-35-14-8-NESTER		10
G26991	Nester Platinum Coils/.035/10mm MWCE-35-14-10-NESTER		10
G26992	Nester Platinum Coils/.035/12mm MWCE-35-14-12-NESTER		10
Snares, Hatch Medical, Inc (Angiotech)			
Catalog #	**Description**		**Quantity**
392006010	EN SNARE/6-10mm		5
392006020	EN SNARE/12-20mm		5
Dilators, Cook Medical			
Catalog #	**Description**		**Quantity**
G10284	AQ$^{®}$ Hydrophilic/6F JCD6.0-35-20-HC		5
G102898	AQ$^{®}$ Hydrophilic/6F JCD8.0-38-20-HC		5
Constrast/Thrombolytics (usually available in standard pharmacy/OR packs)			
Catalog #	**Description**		**Quantity**
	Omnipaque 180		10
	Tenektase (tPA)		10

APPENDIX E: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

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.

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.

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.

ADDITIONAL PROCEDURES

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.

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.

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.