

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



The Prevention of Deep Venous Thrombosis – Inferior Vena Cava Filter (CPG ID: 36)

To establish guidance for 1) anti-thrombotic therapy for the prevention of deep venous thrombosis (DVT) and pulmonary embolism (PE) and 2) the management of inferior vena cava filters (IVCs) placed in the combat theater for the purpose of either primary or secondary prophylaxis of pulmonary embolism.

Contributors

CDR Daniel Grabo, MC, USN
LTC Jason Seery, MC, USA
LCDR Matthew Bradley, MC, USN
MAJ Scott Zakaluzny, MC, USAF

CDR Michel Kearns, MC, USN
CDR Nathaniel Fernandez, MC, USN
CDR Matthew Tadlock, MC, USN

First Publication Date: 01 Jul 2006

Publication Date: 02 Aug 2016

Supersedes CPG dated 24 Apr 2012

TABLE OF CONTENTS

Background	2
Recommendations for DVT Prophylaxis.....	2
Chemical DVT Prophylaxis	3
Retrievable Inferior Vena Cava Filters (RIVCF)	4
Education and Treatment	4
Aeromedical Evacuation Considerations	4
Performance Improvement (PI) Monitoring	5
Population of Interest	5
Intent (Expected Outcomes)	5
Performance/Adherence Metrics	5
Data Source	5
System Reporting & Frequency.....	5
Responsibilities.....	6
References.....	6
Appendix A: Prevention of Venous Thromboembolism Guidelines.....	9
Appendix B: IVCF Recommendations	11
Appendix C: Additional Information Regarding Off-label Uses in CPGs.....	12

BACKGROUND

Trauma patients are known to be at high risk for Venous Thromboembolism (VTE) including Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE). Major trauma patients can have up to 58% incidence of DVT.¹ Sevitt and Gallagher reported an even higher incidence (65%) in injured and burned patients and reported a 16.5% incidence of PE found at autopsy in this cohort of patients.^{2,3}

In addition to the hypercoagulable state induced by severe injury in trauma, combat casualties have additional risk factors for DVT, including:^{1,4-8}

- Early transfusion of blood products (≤ 24 hours);
- Transfusion of old blood (≥ 28 days);
- Multiple and/or above the knee amputations

The use of Fresh Frozen Plasma (FFP) outside of large volume blood product transfusion (less than 4 U PRBC's) incurs an increased risk of VTE.⁹ Early prophylaxis in this patient population is recommended provided hemostasis has been achieved.

The nature of the current combat theater has provided our deployed medical team's ample opportunity to care for children injured as non-combatants. The incidence of DVT after trauma is much lower (6.2%) than that of adults in the civilian literature.¹⁰ The presence of multiple risk factors including immobility and central venous line, however, were associated with the development of DVT in pediatric trauma patients.

There is an increasing recognition of DVT in individuals who complete an extended period of travel on an airplane. One study noted a 10% prevalence of asymptomatic DVT in individuals undergoing flights of 8 hours or more.¹¹ Combat casualties are at high risk for VTE during recovery and evacuation, which can be associated with long flights and immobility, thus it is important to start VTE prophylaxis as soon as clinically possible.¹²

Landstuhl Regional Medical Center is uniquely positioned to receive patients who have undergone extensive periods of travel prior to admission.

Different medical societies and working groups have published varying recommendations for DVT prophylaxis.^{13,14} The clinical guidance recommended here represent the guidelines with either a higher level of scientific evidence supporting the recommendation, or the more conservative recommendation. It is recommended to begin DVT prophylaxis therapy as soon as coagulopathy is corrected in patients not otherwise at increased risk of bleeding.

RECOMMENDATIONS FOR DVT PROPHYLAXIS

Unless contraindicated by lower extremity injury, all trauma patients should receive:

1. Sequential Compression Device (SCD) therapy as primary DVT prophylaxis in addition to;
2. Low dose Unfractionated Heparin (UFH)¹³⁻¹⁵; or
3. Low Molecular Weight Heparin (LMWH), Enoxaparin 30mg subcutaneous (SC) twice daily.¹⁶
4. Alternatively, low doses LMWH such as Dalteparin 5000 U SC or Enoxaparin 40mg SC can be given daily and in one study has a lower incidence of DVT when compared to 30mg BID dosing in post-operative patients.^{14,17,18}

5. Unfractionated Heparin (5000 U) administered subcutaneously three times daily has been demonstrated to be as effective as or at least non-inferior to Enoxaparin in the prevention of DVT in trauma patients.^{19,20}

Consideration should be given to the use of LMWH in patients with impaired renal function (CrCL=30ml/min or less), as there is a concern for LMWH accumulation and increased risk of bleeding.

1. Despite this concern, no clear evidence exists for dose modification or contraindication to the use of LMWH for DVT prophylaxis in renal impaired patients.²¹
2. Godat et al. reported, however, that trauma patients who are considered to be at the highest risk to develop VTE (especially spinal cord injury with/without pelvic fracture) are at the greatest risk during the first three months after injury and that this risk decreases at six months post injury.²³

The role of **duplex ultrasound** in the diagnosis of DVT should be reserved for the symptomatic patient. Serial screening duplex ultrasound for the diagnosis of DVT is not recommended.¹⁴

CHEMICAL DVT PROPHYLAXIS

Provided coagulopathy and ongoing bleeding is corrected, chemical DVT prophylaxis (<48 hours post injury) has been shown to be safe after blunt solid organ injuries.^{24,25}

Chemical DVT prophylaxis (<48-72 hours) following traumatic brain injury with intracranial hemorrhage does not increase the progression of intracranial bleed.^{26,27} Prior to starting chemical DVT prophylaxis, you should:

1. Consult a Neurosurgeon.
2. Obtain a stable CT scan of the head at 24 hours post injury.

Prophylaxis should be withheld in the setting of progression of intracranial hemorrhage or presence of an intracranial monitor.

Modification of enoxaparin dosing to 40mg daily in the combat casualty requiring an epidural pain catheter does not increase the incidence of venous thromboembolism.²⁸

Inferior Vena Cava Filter (IVCF) placement in the combat theater may be used for:

1. Primary Prophylaxis (no evidence of VTE disease at the time of placement).
2. Secondary Prophylaxis (documented DVT) of PE in the polytrauma patient.

Patients felt to be at particularly **high risk for VTE development** and who have a clinical contraindication to prophylactic anticoagulation are the most likely to have an IVCF placed.

Most series examining the use of **IVCF placement for primary prophylaxis of PE** in the trauma patient support a low rate of subsequent PE (1.6%), although the studies are of variable design and a strong consensus supporting this clinical practice cannot be made based upon available data.²⁹

There is no evidence that **prophylactic use of IVCF** is associated with a decreased PE rate or fatal PE rate. It should be noted that when IVCF are placed they are done so to prevent FATAL Pulmonary Emboli as DVT and PE still can occur.³⁰⁻³⁴

IVCF has no benefit in the prevention of DVTs and may be associated with the development of IVC and Deep Venous Thrombosis.^{14,35}

RETRIEVABLE INFERIOR VENA CAVA FILTERS (RIVCF)

The vast majority of IVCF devices placed in the combat theater are Retrievable Inferior Vena Cava Filters (RIVCF).

RIVCF are preferred to avoid some of the long-term complications of filter placement. Additionally, many patients only need this form of VTE prophylaxis for a defined period of time early after injury.

Despite successful removal of IVCF beyond 180 days and high success and low complication rate for attempted **IVCF removal**, rates of eventual removal of RIVCFs in multiple studies of trauma patients in the United States have been as low as 14% to 22%.^{36,37,38,39,40}

Combat injured patients from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) who had RIVCFs placed have an overall retrieval rate of 18%.⁴¹

It should be noted however; that the majority of patients was lost to follow up or did not have filters removed due to ongoing indications for use (82%). Therefore, the overall retrieval technical success rate may be much higher. Most series support removal of the most commonly used RIVCFs as early as they are no longer necessary and no later than approximately three months.⁴² While it is possible to remove any of these later than this time period, the technical success declines significantly as potential complications associated with removal increase. Clear electronic documentation and a dedicated tracking system at the final CONUS MTF must be in place to improve retrieval rates and minimize loss to follow up.⁴³

EDUCATION AND TREATMENT

Refer to [Appendix A](#) for specific guidance on different subsets of patients after various surgical procedures.

Refer to [Appendix B](#) for additional recommendations regarding IVC filters.

AEROMEDICAL EVACUATION CONSIDERATIONS

1. Aeromedical Evacuation (AE) from any area of responsibility to continental U.S. can require multiple flights over the course of days before the patient arrives at his or her final destination.
2. There is a clear association between long-distance travel and an increased risk of VTE, even in a “healthy traveler.”
3. Stresses of flight such as prolonged immobility and decreased humidity may contribute to VTE formation, especially in groups who already carry a high risk (trauma patients, recent surgeries, long bone fractures, smokers, pregnancy or post-partum, recent Myocardial Infarction, active cancer, presence of splint or cast, etc.).
4. Prophylaxis is essential to reduce the risk of VTE associated morbidity and mortality in all AE patients.
 - a. AE crews will encourage patient ambulation every 2 hours for patients whose condition allows.
 - b. SCD use should be universal for inpatients unless contraindicated by injury pattern. The Kendal SCD Express compression system is approved for use on military aircraft.
 - c. Chemical VTE prophylaxis is also recommended as above for all trauma or medical inpatients unless specifically contraindicated by the medical condition such as ongoing bleeding or coagulopathy.
5. AE Patients with KNOWN acute VTE should be treated prior to flight unless there is a clear contraindication.
 - a. Treatment depends on the clinical situation, but may include low-molecular-weight Heparin, Fondaparinux, oral Xa inhibitors, or Unfractionated Heparin.
 - b. Oxygen and continuous pulse-oxygenation monitoring should be available during AE for patients with known VTE in case supportive measures are needed.
 - c. In the case of known or suspected Pulmonary Embolism, a Cabin Altitude Restriction should be considered to mitigate the effects of altitude on oxygenation and respiration.

- d. Addition of a Critical Care Air Transport Team should also be considered in cases of PE with significant respiratory or hemodynamic compromise.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All trauma patients admitted to Role 2 or higher.

INTENT (EXPECTED OUTCOMES)

1. All patients in population of interest receive DVT prophylaxis with sequential compression device within 24 hours of injury.
2. All patients in population of interest start chemoprophylaxis (Heparin, Lovenox) within 48 hours of injury or contraindication documented.
3. When IVCF is inserted, there is documentation in the medical record regarding the indication for procedure, whether the IVCF is retrievable, manufacturer, brand, serial number, lot number, and exact location of placement.
4. Retrievable IVC filters are removed within 6 months.

PERFORMANCE/ADHERENCE METRICS

1. Number and percentage of patients in the population of interest who start DVT prophylaxis with sequential compression device within 24 hours of injury.
2. Number and percentage of patients in the population of interest who receive DVT chemoprophylaxis within 48 hours (Heparin, Lovenox) or have contraindication documented.
3. Number and percentage of patients who receive IVC filter placement who have complete documentation of indication for procedure, whether the IVCF is retrievable, manufacturer, brand, serial number, lot number, and exact location of placement.
4. Number and percentage of retrievable IVC filters placed that are removed within 6 months.

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 JTS Chief, JTS Program Manager and the JTS PI Branch.

RESPONSIBILITIES

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

All Health Care Providers will:

- Become familiar with the guidelines for the prevention of DVT (see Appendix A).
- Appropriately manage patients who may be at risk of developing DVT.
- Provide feedback on these guidelines and suggestions for changes to the CPG to the JTS Chief.

The senior surgeon and/or Intensivist at each Role 3 facility will:

- Review all thromboembolic events in the Level III facility to assess ways to reduce the risk to the patient.
- Coordinate with the JTS Performance Improvement Division Chief on the appropriateness of the guidelines being used and provide input for updates on an as needed basis.

REFERENCES

1. Geerts WH, Code KJ, Jay RM, et al: A prospective study of venous thromboembolism after major trauma. *N Engl J Med* 1994;331(24):1601-1606.
2. Sevitt S, Gallagher N. Venous thrombosis and pulmonary embolism. A clinico-pathological study in injured and burned patients. *Br J Surg* 1961;48:475-489.
3. Godat LN Kobayashi L, Chang DC et al. Can we ever stop worrying about venous thromboembolism after trauma? *J Trauma* 2015;78(3):475-480.
4. Differding JA, Underwood SJ, Van PY, et al. Trauma induces a hypercoagulable state that is resistant to hypothermia as measured by thromboelastogram. *Am J Surg* 2011;201(5):587-591.
5. Gearhart MM, Luchette FA, Proctor MC, et al. The risk assessment profile score identifies trauma patients at risk for deep venous thrombosis. *Surgery* 2000;128(4):631-637.
6. Spinella PC, Carroll CL, Staff I, et al. Duration of red blood cell storage is associated increased incidence of deep venous thrombosis and in hospital mortality in patients with traumatic injuries. *Critical Care* 2009;13(5):R151.
7. Hutchinson TN, Krueger CA, Berry, JS, et al. Venous thromboembolism during combat operations: a 10-y review. *J Surg Res* 2014;187(2):625-630.
8. Knudson MM: Thromboembolism after trauma: an analysis of 1602 episodes from the American College of Surgeons National Trauma Data Bank. *Ann Surg* 2004: 490-496.
9. Zander AL, Olson EJ, Van Gent JM, et al. Does resuscitation with plasma increase the risk of venous thromboembolism? *J Trauma* 2015;78(1):39-43.
10. Hanson SJ, Punzalan RC, Greenup RA, et al. Incidence and risk factors for venous thromboembolism in critically ill children after trauma. *J Trauma* 2010;68(1):52-56.
11. Scurr JH; Machin SJ; Bailey-King S; Mackie IJ; McDonald S; Smith PD, "Frequency and Prevention of Symptom-less Deep Venous Thrombosis in Long Haul Flights: A Randomized Trial, *Lancet* 2001; 357:1485-1489.

12. Holley AB, Petteys S, Mitchell JD, et al. Thromboprophylaxis and VTE rates in soldiers wounded in Operation Enduring Freedom and Operation Iraqi Freedom. *Chest* 2013;144(3):966-973.
13. Rogers FB, Cipolle MD, Velmahos G, et al. Practice management guidelines for the prevention of venous thromboembolism in trauma patients: the EAST practice management guidelines work group. *J Trauma* 2002;53(1):142-164.
14. Guyatt GH, Akl EA, Crowther M, et al. Antithrombotic therapy and prevention of thrombosis, 9th edition: American College of Chest Physicians evidence based clinical practice guidelines. *Chest* 2012;141;(2)7S-47S.
15. Kakkos SK, Caprini JA, Geroulakos G, et al. Combined intermittent leg compression and pharmacological prophylaxis for the prevention of venous thromboembolism in high risk patients. *Cochrane Database Syst Rev* 2008, Issue 4. Art No. CD005258.
16. Geerts WH, Jay RM, Code KJ, et al: A comparison of low-dose heparin with low-molecular weight heparin as prophylaxis against venous thromboembolism after major trauma. *N Engl J Med* 335:701-7, 1996.
17. Cothren CC, Smith WR, Moore EE, et al. Utility of once-daily dose of low-molecular weight heparin to prevent venous thromboembolism in multisystem trauma patients. *World J Surg* 2007;31(1):98-104.
18. Riha GM, Van PY, Differding JA, et al. Incidence of deep venous thrombosis is increased with 30 mg twice daily dosing of enoxaparin compared with 40 mg daily. *AM J Surg* 2012;203(5):598-602.
19. Arnold JD, Dart BW, Barker DE, et al. Unfractionated heparin three times a day versus enoxaparin in the prevention of deep venous thrombosis in trauma patients. *Am Surg* 2010;76(6):563-570.
20. Olson EJ, Bandle J, Calvo RY, et al. Heparin versus enoxaparin for prevention of thromboembolism after trauma: A randomized noninferiority trial. *J Trauma*. 2015;79(6):961-969.
21. Nagge J, Crowther M, Hirsh J. Is impaired renal function a contraindication to the use of low molecular-weight heparin? *Arch Int Med* 2002;162(22):2605-2609.
22. Lim W, Dentali F, Eikelboom JW, et al. Meta-analysis: low-molecular weight heparin and bleeding in patients with severe renal insufficiency. *Ann Int Med* 2006;144(9):673-684.
23. Godat LN, Kobayashi L, Chang DC, et al. Can we ever stop worrying about venous thromboembolism after trauma? *J Trauma*. 2015;78(3):475-481.
24. Rostas JW, Manley J, Gonzalez RP, et al. The safety of low molecular weight heparin after blunt liver and spleen injuries. *Am J Surg* 2015 Jul;210(1):31-34.
25. Joseph B, Pandit V, Harrison C, et al. Early thromboembolic prophylaxis in patients with blunt solid abdominal organ injuries undergoing nonoperative management: is it safe? *Am J Surg* 2015;209(1):194-198.
26. Norwood SH, McAuley CE, Berne JD, et al. Prospective evaluation of the safety of enoxaparin prophylaxis for venous thromboembolism in patients with intracranial hemorrhagic injuries. *Arch Surg* 2002;137(6):696-701.
27. Koehler DM, Shipman J, Davidson MA, et al. Is early venous thromboembolism practice safe in trauma patients with intracranial hemorrhage? *J Trauma* 2011;70(2):324-329.
28. Caruso JD, Elster EA, Rodriguez CJ. Epidural placement does not result in an increased incidence of venous thromboembolism in combat-wounded patients. *J Trauma* 2014;77(1):61-66.
29. Cherry RA, Nichols PA, Snavely TM, et al. Prophylactic inferior vena cava filters: do they make a difference in trauma patients? *J Trauma* 2008;65(3):544-548.

30. Kalva SP, Athanasoulis CA, Chieh-Min F, et al. Recovery vena cava filter: experience in 96 patients. *Cardiovasc Intervent Radiol* 2006;29:559-564.
31. Miyahara T, Miyata T, Shigematsu K, et al. Clinical outcome and complications of temporary inferior vena cava filter placement. *J Vasc Surg* 2006;44:620-624.
32. Arsch MR. Initial experience in humans with a new retrievable inferior vena cava filter. *Radiology* 2002;225(3):835-844.
33. White RH, Zhou H, Kim J, et al. A population-based study of the effectiveness of inferior vena cava filter use among patients with venous thromboembolism. *Arch Int Med* 2000;160(13):2033-2041.
34. PREPIC Study Group. Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. *Circulation* 2005;112(3):416-422.
35. Baglin TP, Brush J, Streiff M. Guidelines on use of vena cava filters. *Br J Haematol* 2006;134(6):590-595.
36. Binkert CA, Sasadeusz K, Stavropoulos SW. Retrievability of the Recovery vena cava filter after dwell times longer than 180 days. *J Vasc Interv Radiol* 2006;17:299-302.
37. Kim HS, Young MJ, Narayan AK, et al. A comparison of clinical outcomes with retrievable and permanent inferior vena cava filters. *J Vasc Interv Radiol* 2007;19(3):393-399.
38. Grande WJ, Trerotola SO, Reilly PM, et al. Experience with the Recovery Filter as a retrievable inferior vena cava filter. *J Vasc Interv Radiol* 2005;16(9):1189-1193.
39. Hoff WS, Hoey BA, Wainwright GA, et al. Early experience with retrievable inferior vena cava filters in high risk trauma patients. *J Am Coll Cardiol* 2004;199(6):869-874.
40. Karmy-Jones R, Jurkovich GJ, Velmahos GC, et al. Practice patterns and outcomes of retrievable vena cava filters in trauma patients: an AAST multicenter study. *J Trauma* 2007;62(1):17-24.
41. Johnson ON, Gillespie DL, Aidinian G, et al. The use of retrievable inferior vena cava filters in severely injured military trauma patients. *J Vasc Surg* 2009;49:410-416.
42. Morris CS, Rogers FB, Najarian KE, et al. Current trends in vena caval filtration with the introduction of a retrievable filter at a level I trauma center. *J Trauma* 2004;57(1):32-36.
43. Lucas DJ, Dunne JR, Rodriguez CJ, et al. Dedicated tracking of patients with retrievable inferior vena cava filters improves retrieval rates. *Am Surg* 2012;78(8):870-874.

APPENDIX A: PREVENTION OF VENOUS THROMBOEMBOLISM GUIDELINES

RISK GROUP	PROPHYLACTIC MEASURES
TRAUMA PATIENTS	
<ul style="list-style-type: none"> ▪ Emergency trauma surgical procedures in patients with prohibitive risk of bleeding, or ongoing coagulopathy ▪ Emergency trauma surgical procedures in all patients, except patient with prohibitive risk of bleeding (once coagulopathy not present) ▪ Isolated major orthopedic surgery of extremities, spine, and pelvis 	<ul style="list-style-type: none"> ▪ SCD (sequential compression device) until able to be anticoagulated (ideally start Lovenox within 12 hours of cessation of coagulopathy); see IVC filter and Duplex screening sections below. ▪ SCD (unless contraindicated by injury) + Lovenox 30 mg SC BID or 40mg SC QD; alternatively Heparin 5000 U SC q 8 hours ▪ SCD (unless contraindicated by injury) + Lovenox 30 mg SC BID
IVC FILTER PLACEMENT	
<p>Patients with:</p> <ol style="list-style-type: none"> 1. Recurrent PE despite full anticoagulation 2. Proximal DVT and contraindications for full anticoagulation 3. Proximal DVT and major bleeding while on full anticoagulation 4. Progression of iliofemoral clot despite anticoagulation <p>Patients with established DVT or PE and:</p> <ol style="list-style-type: none"> 5. Large free-floating thrombus in the iliac vein or IVC 6. Following massive PE in which recurrent emboli may prove fatal 7. During/after surgical embolectomy <p>Very High Risk Patients: those who cannot receive anticoagulation because of increased bleeding risk and :</p> <ol style="list-style-type: none"> 8. Severe closed head injury (GCS<8) 9. Incomplete spinal cord injury with paraplegia or quadriplegia 10. Complex pelvic fractures with associated long-bone fractures 11. Multiple long-bone fractures 	<ul style="list-style-type: none"> ▪ Placement of retrievable IVC filter (RIVCF) ▪ Document if the IVCF is retrievable or not, manufacturer, brand, MRI compatibility, serial number, lot number and exact location in record and TMDS; PE may still occur despite IVC filter ▪ “Extended” indications for placement of IVC filter for patients with established DVT or PE ▪ Consideration of placement of prophylactic placement of IVC filter.
ROLE OF DUPLEX SCREENING	
<ul style="list-style-type: none"> ▪ Asymptomatic patients ▪ Symptomatic patients 	<ul style="list-style-type: none"> ▪ Serial duplex ultrasound imaging of high-risk patients is not recommended. ▪ Duplex ultrasound may be used without confirmatory venography.
GENERAL, VASCULAR, UROLOGIC SURGERY	
LOW RISK:	
<p>Minor procedure in patients < 40 years, no risk factors</p>	<p>Early mobilization</p>
MODERATE RISK:	
<ul style="list-style-type: none"> ▪ Minor procedure with additional risk factors for thrombosis; ▪ Non major surgery in patients 40-60 years, with no additional risk factors; ▪ Major surgery in patients < 40 years with no additional risk factors) 	<ul style="list-style-type: none"> ▪ SCD + Unfractionated Heparin 5000 units SCq 8 hours or Lovenox 40 mg SC QD ▪ Chemical DVT prophylaxis is withheld in patients with high risk of bleeding.

RISK GROUP	PROPHYLACTIC MEASURES
HIGH RISK:	
<ul style="list-style-type: none"> ▪ Non major surgery in patients > 60 years or have additional risk factors; ▪ Major surgery in patients > 40 years or have additional risk factors 	<ul style="list-style-type: none"> ▪ SCD + Unfractionated Heparin 5000 units SC q 8 hours or Lovenox 40 mg SC QD ▪ Chemical DVT prophylaxis is withheld in patients with high risk of bleeding.
NEUROSURGERY	
<ul style="list-style-type: none"> ▪ Intracranial neurosurgical procedures ▪ High Risk neurosurgery patients 	<ul style="list-style-type: none"> ▪ SCD ▪ Chemical DVT prophylaxis following stable CT scan in consultation with neurosurgeon

APPENDIX B: IVCF RECOMMENDATIONS

1. All IVCFs placed in the combat theater should be retrievable.
2. Documentation detailing the IVCF brand, model, MRI compatibility, and exact location of placement should be documented in ALTA T or TC2.
3. All RIVCFs placed in the combat theater should be removed as soon as contraindications to chemical prophylaxis of VTE disease no longer exist or there is no longer a need for VTE prophylaxis. Exceptions include those that were placed for secondary prophylaxis in a patient who demonstrated new VTE disease while on therapeutic anticoagulation or in patients who are still deemed to be high risk.
4. All RIVCFs should be removed within three months unless a long term indication for their continued use is present.
5. The decision to remove an RIVCF placed in the combat theater (versus leaving it in place permanently) should be made at the first CONUS Level V MTF the patient transitions through while returning from deployment. When possible, the removal should take place at this same facility prior to transition to the next level of care. This approach decreases the chance that a decision will be deferred until removal becomes technically prohibitive.
6. **The presence of a RIVCF in a patient receiving care at the Level IV MTF should be made known to the receiving Level V MTF. Typically, retrieval of the RIVCF will be accomplished at the Level V MTF.**
7. Any patient with a known DVT and without a current contraindication to therapeutic anticoagulation who has an IVCF in place should receive full dose anticoagulation. This is preferably accomplished with Coumadin to target an INR of 2.0-3.0. If further surgical procedures are planned, consideration may also be given to the use of low molecular weight heparin dosed at 1 mg/kg bid or an unfractionated heparin drip until such time as the use of Coumadin is felt to be appropriate.
8. The presence of an IVCF, brand, model, MRI compatibility, whether or not it is retrievable, its exact location and the date of insertion should be clearly annotated in TMDS and again in AHLTA when the patient has returned to the United States.
9. Efforts should be made in the future to standardize the type of RIVCF used at all combat theater locations.

APPENDIX C: 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.