

# C.E.C.T. Therapy



## ActiveCare+S.F.T. vs Enoxaparin (The S.A.F.E. Study)

### DVT Prevention in Joint Arthroplasty Patients

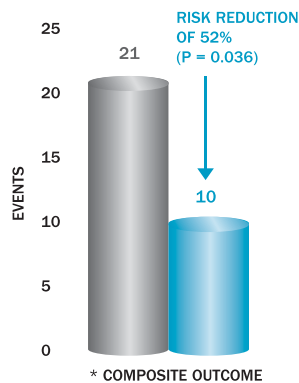
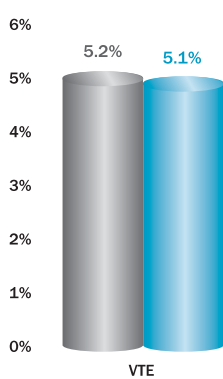
Prospective, randomized, treatment controlled & multi-center study  
(In-hospital and post-discharge prophylaxis)

**PI: Dr. CW Colwell Jr.** - Scripps Clinic - La Jolla, California

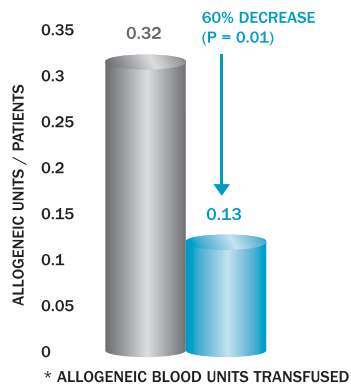
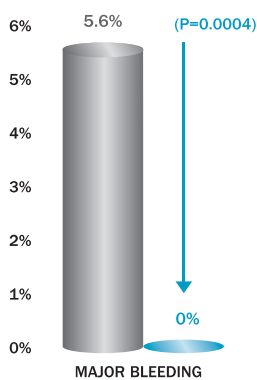
#### Sites involved:

Clifford W. Colwell Jr., MD, Scripps Clinic - La Jolla, CA  
 Mark I. Froimson, MD, MBA, Cleveland Clinic - Cleveland, OH  
 Michael A. Mont, MD, Sinai Hospital - Baltimore, MD  
 Merrill A. Ritter, MD, St. Francis Hospital - Mooresville, IN  
 Robert T. Trousdale, MD, Mayo Clinic - Rochester, MN  
 Knute O. Buehler, MD, St. Charles Medical Center - Bend, OR  
 Andrew Spitzer, MD, Cedars-Sinai Medical Center - Los Angeles, CA  
 Thomas K. Donaldson, MD, Loma Linda University Medical Center - Loma Linda, CA  
 Douglas E. Padgett, MD, Hospital for Special Surgery - New York, NY

Results: Control group - Enoxaparin: 194 patients, VTE: 5.2%, Major Bleeding: 5.6%  
 Study group - ActiveCare+S.F.T. (± Aspirin): 198 patients, VTE: 5.1%, Major Bleeding: 0.0%



- VTE rate was **similar** in both groups
- Major Bleeding was **reduced to zero** in the **ActiveCare+S.F.T.** group.
- Composite outcome events (VTE + Major Bleeding) show a **52% decrease** in the **ActiveCare+S.F.T.** group.
- Enoxaparin use increased the consumption of blood products by 50% and caused a **250% increase** in transfused allogeneic blood units.



■ ActiveCare+S.F.T.  
 ■ Enoxaparin

\* Data on file. MCS Ltd. (2010)

Colwell, C.W. Jr., Froimson M.I., Mont M.A., Ritter M.A., Trousdale R.T., Buehler K.C., Spitzer A., Donaldson T.K., Padgett D. E., Thrombosis prevention after total hip arthroplasty: a prospective, randomized trial comparing a mobile compression device with LMWH. *J Bone Joint Surg Am* 2010;92(3):527-535

■ **ActiveCare+S.F.T.**® is the brand name of a medical device classified as Continuous Enhanced Circulation Therapy (**C.E.C.T.**).



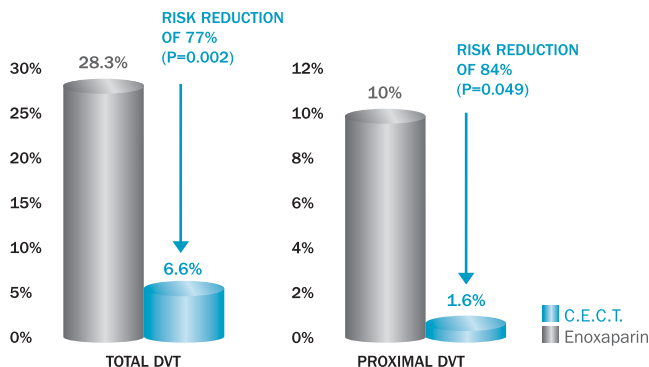
## C.E.C.T. vs Enoxaparin

### DVT Prevention in Joint Arthroplasty Patients

Prospective, randomized, treatment controlled study  
(In-hospital Prophylaxis)

PI: **Dr. N Halperin** - Assaf Harofe Medical Center - Be'er Yakov, Israel

Results: Control group - Enoxaparin: 60 patients, DVT: 28.3% (Venography)  
Study group - ActiveCare (+Aspirin): 61 patients, DVT: 6.6% (Venography)



Gelfer Y., Tavor H., Oron A., et al. Deep vein thrombosis prevention in joint arthroplasties: continuous enhanced circulation therapy vs LMWH. *J Arthroplasty* 2006;21(2):206-214

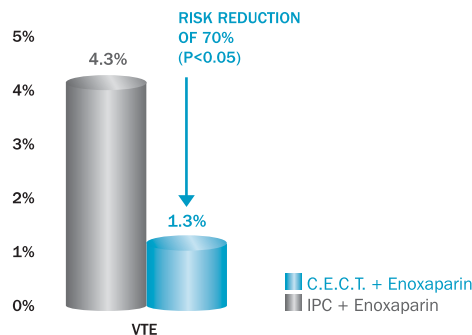
## C.E.C.T.+Enoxaparin vs IPC+Enoxaparin

### DVT Prevention in Joint Arthroplasty Patients

Non-randomized, comparative (sequential) performance study

PI: **Dr. M Froimson** - Cleveland Clinic - Cleveland, Ohio

Results: Control group - IPC+Enoxaparin: 1354 patients, VTE=4.3%, PE=0.7% (9 Pt.)  
Study group - ActiveCare+Enoxaparin: 223 patients, VTE= 1.3%, PE= 0.0%



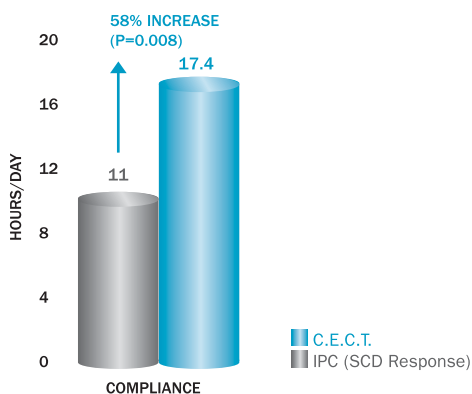
Froimson M., Murray T., Fazekas A. Venous thromboembolic disease reduction with a portable pneumatic compression device. *J Arthroplasty* 2009;24(2):310-316

## C.E.C.T. vs IPC

### Compliance in Trauma Patients

PI: **Dr. LA Killweich** - UTMB - Galvestone, Texas

Results: More than 6 hr. difference in daily treatment (58%)



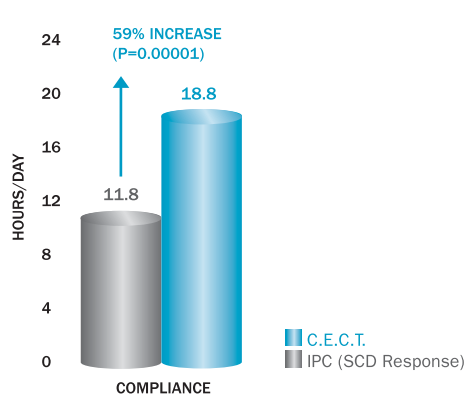
Murakami M., McDill TL., Cindrick-Pounds L., et al. Deep venous thrombosis prophylaxis in trauma: improved compliance with a novel miniaturized pneumatic compression device. *J Vasc Surg* 2003;38:923-927

## C.E.C.T. vs IPC

### Compliance in Gynecology Patients

PI: **Dr. LA Killweich** - UTMB - Galvestone, Texas

Results: More than 7 hr. difference in daily treatment (59%)



Kahn M., Lord C., Murakami M., et al. Deep venous thrombosis prophylaxis in gynecologic surgery: improved compliance with a novel miniaturized pneumatic compression device. *J Pelvic Med Surg* 2003;9(suppl 1):S6

## C.E.C.T. vs IPC

### Hemodynamic Comparison

PI: **Dr. LA Killweich** - UTMB - Galvestone, Texas

Results: 57% Relative improvement in Peak Venous Velocity (PVV) at common femoral vein (CFV) with calf sleeve when ActiveCare was used

Murakami M., McDill TL., Cindrick-Pounds L., et al. Deep venous thrombosis prophylaxis in trauma: improved compliance with a novel miniaturized pneumatic compression device. *J Vasc Surg* 2003;38:923-927

**Continuous Enhanced Circulation Therapy (C.E.C.T.)** is a new class of miniature mobile devices that can deliver the therapy throughout the full course of treatment (in and out of the hospital).

