

THE S.A.F.E. STUDY

ActiveCare+S.F.T.[®] vs Enoxaparin

ActiveCare+S.F.T. compared to enoxaparin for the prevention of
thrombosis after total hip arthroplasty (in-hospital and post-discharge prophylaxis)

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The Journal of Bone and Joint Surgery (AM) Vol. 92, March 2010

Thrombosis Prevention after Total Hip Arthroplasty: A Prospective, Randomized Trial Comparing a Mobile Compression Device with LMWH.



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

OBJECTIVE

To compare the efficacy and safety of **ActiveCare+S.F.T.** therapy versus enoxaparin for VTE prevention after total hip arthroplasty (THA) through ten-day duration of in-hospital and post-discharge prophylaxis.

INCLUSION CRITERIA

Adult patients undergoing elective THA surgery.

DESIGN

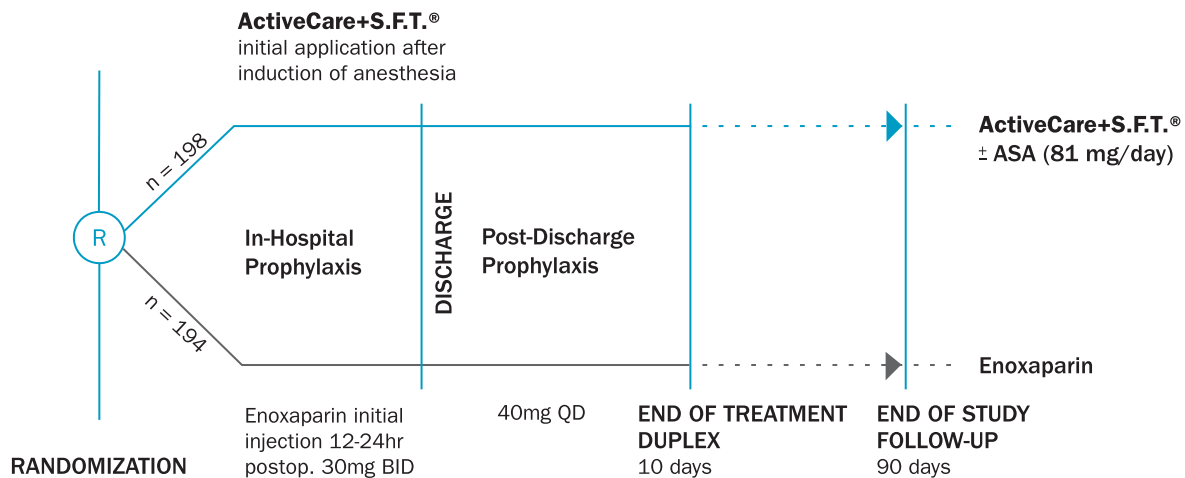
Prospective, randomized, treatment controlled and multi-center study.

ENDPOINTS

Efficacy - VTE: DVT was detected by bilateral duplex scan at the end of prophylaxis.

Clinically suspected PE confirmed with spiral CT lung scan. Any symptomatic VTE events were collected up to 90 days PO.

Safety: Major bleeding complications.



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

RESULTS

Summary - 410 patients were randomized of which 386 patients were evaluable for efficacy (196 in the **ActiveCare+S.F.T.** group and 190 in the enoxaparin group).

392 patients were available for safety (198 in the **ActiveCare+S.F.T.** group and 194 in the enoxaparin group).

Efficacy - There was no statistical difference between the groups in the incidence of venous thromboemboli events.

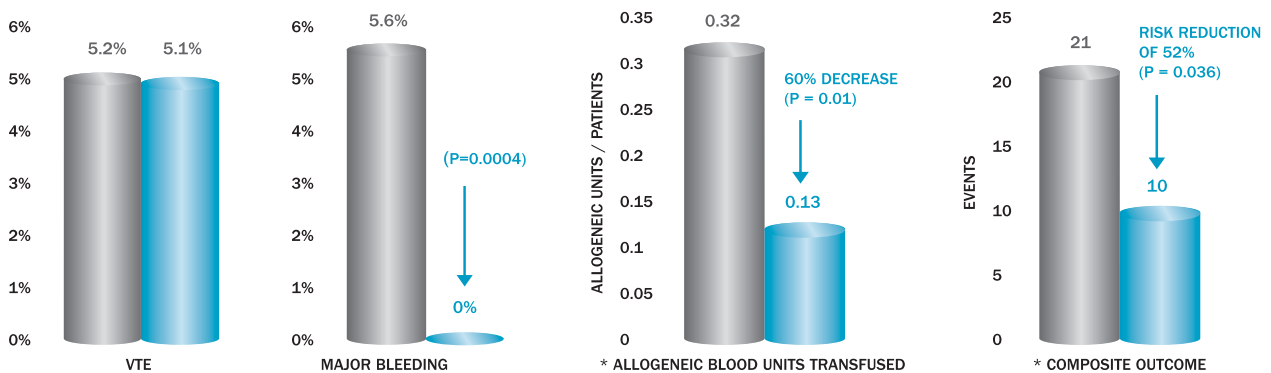
Safety - ActiveCare+S.F.T. showed a significant decrease in major bleeding events versus enoxaparin.

STUDY OUTCOMES

	ActiveCare+S.F.T.®	ENOXAPARIN	P VALUE
VTE	5.1% (10/196)	5.2% (10/190)	n.s.
MAJOR BLEEDING	0% (0/199)	5.6% (11/196)	P=0.0004
ALLOGENEIC BLOOD UNITS TRANSFUSED Per patient per group	0.13 (26/198)	0.32 (63/194)	P=0.01
COMPOSITE OUTCOME	10	21	P=0.036

■ ActiveCare+S.F.T.
■ Enoxaparin

* Data on file. MCS Ltd. (2010)



EVIDENCE-BASED CONCLUSION

No statistical significant differences in VTE rates were observed between the **ActiveCare+S.F.T.** group and the enoxaparin group. However, prophylaxis with **ActiveCare+S.F.T.** was found to be far safer with a significantly lower incidence of associated serious bleeding complications.

TECHNICAL SPECIFICATIONS

INDICATION	DVT prophylaxis, reduction of post-operative pain and swelling, reduction of wound healing time
SIZE	5.3 x 5.3 x 2.4 in (135 x 135 x 60 mm)
WEIGHT	730 g / 1.6 lb (including battery)
POWER INPUT	9.7 VDC
BATTERY*	7.2 V (rechargeable NiMH)
Battery life	5h (after full recharge)
Recharge time	4-5 h
CHARGER	Built-in
MAINS SUPPLY	100-240V, 50/60 Hz
INFLATION MODE	Sequential compression
PRESSURE (preset)	
Calf	50 mmHg (± 10%)
Foot	130 mmHg (± 10%)
Thigh	50 mmHg (± 10%)
COMPRESSION	
DURATION	
Calf	Up to 10 sec
Foot	Up to 6 sec (depending on model)
Thigh	Up to 15 sec (depending on model)
PULSE FREQUENCY	
Calf	1 per minute
Foot	2 per minute
Thigh	1 per minute

*Battery life and recharge may vary depending on usage.

WARNING: Use only the battery pack provided by MCS.

Use of any alternative power source could cause irreparable damage to the system!

All MCS products are LATEX FREE
FDA CLASS II Prescription device

