

# THE S.A.F.E. STUDY

## ActiveCare+S.F.T.<sup>®</sup> vs Enoxaparin

**ActiveCare+S.F.T.<sup>®</sup> compared with enoxaparin for the prevention of venous thromboembolism after total hip arthroplasties (in hospital and post-discharge prophylaxis)**

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**MCS**  
Medical Compression  
Systems Inc.

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



# OBJECTIVE

To compare the efficacy and safety of the **ActiveCare+S.F.T.**<sup>®</sup> system with low-molecular-weight heparin for VTE prevention after THA, through ten-day duration of in-hospital and post-discharge prophylaxis.

# INCLUSION CRITERIA

Adult patients undergoing elective THA surgery.

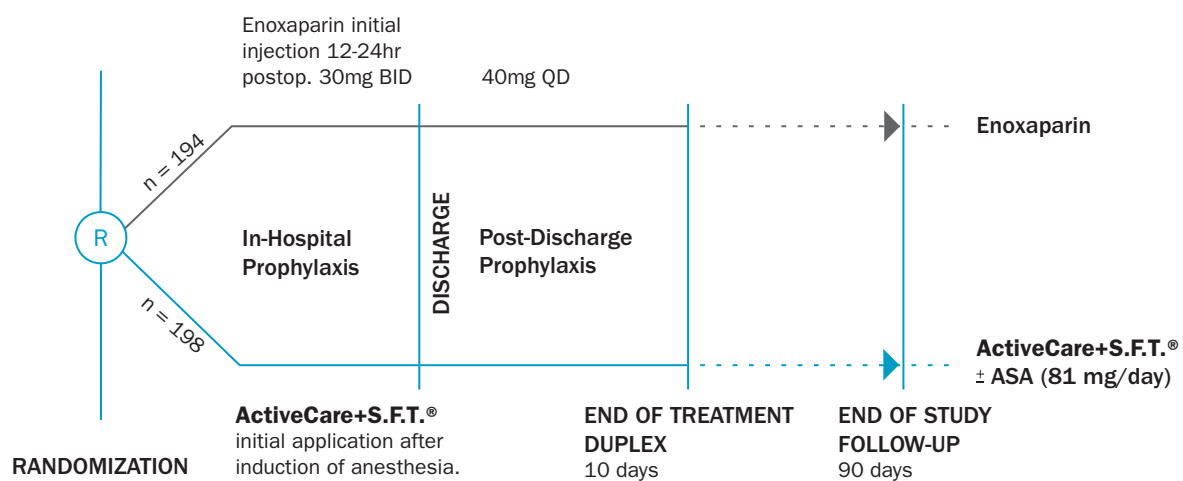
# DESIGN

A prospective, randomized, controlled 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.



# RESULTS

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

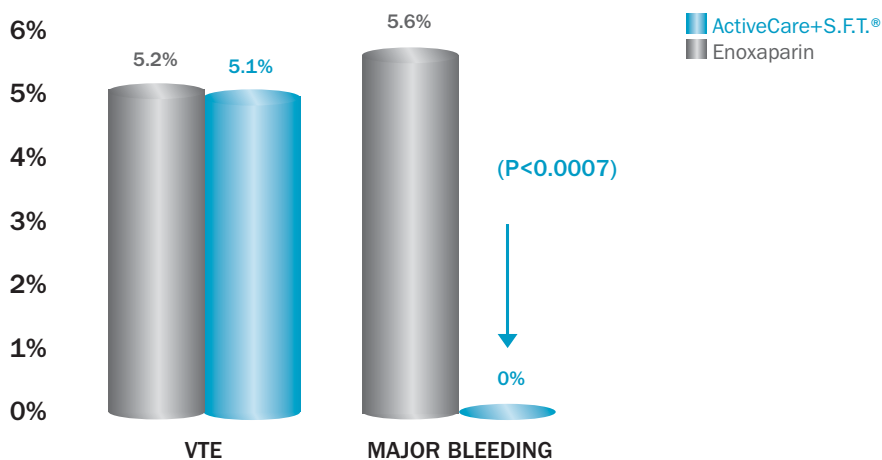
392 patients were available for safety (198 in **ActiveCare+S.F.T.**® group and 194 in LMWH group).

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

**Safety** - The **ActiveCare+S.F.T.**® showed a significant decrease in major bleeding events versus Enoxaparin.

# STUDY OUTCOMES

	ActiveCare+S.F.T.® PROTOCOL	ENOXAPARIN PROTOCOL	SIGNIFICANCE P VALUE
VTE	5.1% (10/196)	5.2% (10/190)	n.s.
MAJOR BLEEDING	0% (0/199)	5.6% (11/196)	P<0.0007



# 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 the **ActiveCare+S.F.T.**® system was found to be far safer with a significantly lower incidence of associated serious bleeding complications.

# TECHNICAL SPECIFICATIONS

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



## **ActiveCare+S.F.T.®**

Synchronized Flow Technology

**Continuous  
Enhanced  
Circulation  
Therapy System**

