

THE S.A.F.E. STUDY

ActiveCare+S.F.T.® vs Enoxaparin

DVT Prevention in Joint Arthroplasty Patients

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

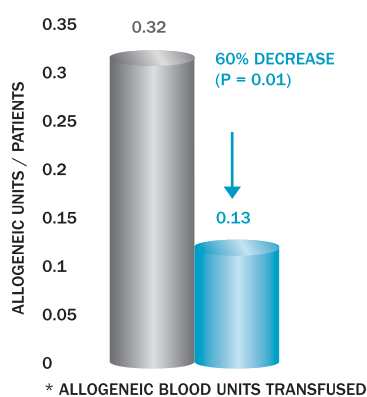
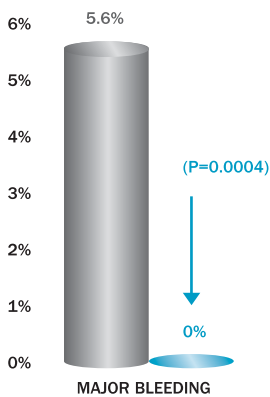
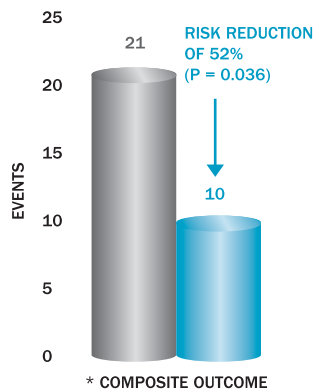
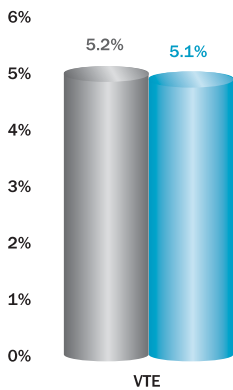
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Results: Control group - Enoxaparin: 194 patients, VTE: 5.2%, Major Bleeding: 5.6%
 Study group - **ActiveCare+S.F.T.** (± Aspirin): 198 patients, VTE: 5.1%, Major Bleeding: 0.0%



- 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)

Objective

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

Design

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

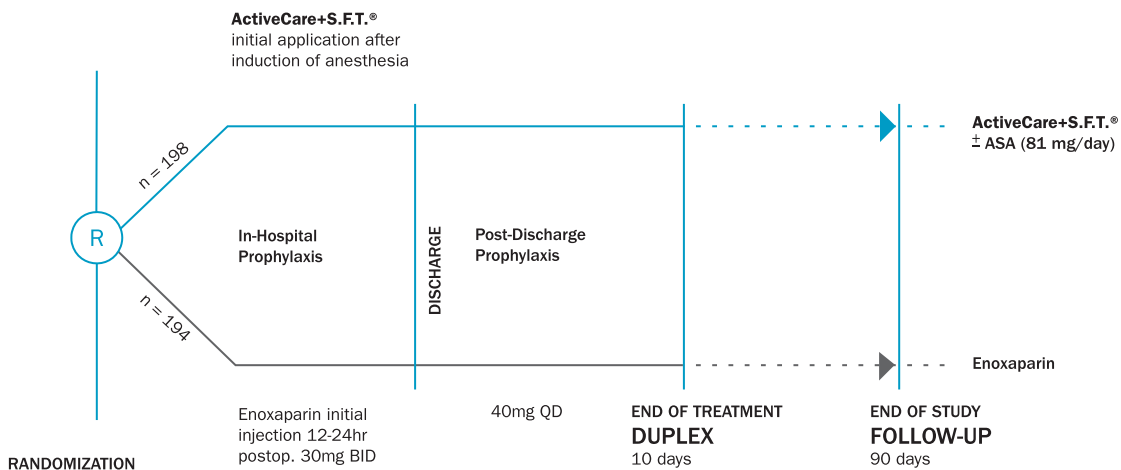
Endpoints

Efficacy - VTE: DVT was detected by bilateral duplex scan at the end of prophylaxis. Clinically suspected PE was confirmed with spiral CT lung scan. Any symptomatic VTE events were collected up to 90 days PO.

Safety - Major bleeding complications

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.



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