



RISE Clinical Study

for StarClose SE Vascular Closure System

Conclusion

- The StarClose SE Vascular Closure System is both safe and effective allowing patients who have undergone diagnostic endovascular catheterization procedures to ambulate and be eligible for discharge as soon as possible after device placement.

Description

- RISE is a prospective, multi-center (11 United States clinical centers), single-arm, post-market study with 171 patients enrolled between April and November 2006
- The RISE Clinical Study objective is to evaluate the safety and efficacy of StarClose in the femoral artery in subjects who are ambulated early post-percutaneous, cardiac or peripheral vascular, diagnostic catheterization procedure

Study Endpoints

Primary Endpoint

- Time to Ambulation (TTA)
 - Elapsed time between hemostasis and first observed ambulation of 20 feet (6 metres) without the occurrence of re-bleeding

Secondary Endpoints

- Time to Hemostasis (TTH)
- Time to Dischargeability (TTD)
 - post-deployment
 - post-ambulation
- Device success
- Procedural success
- Overall rate of major and minor vascular complications

Patient Populations

Final Analysis Set (FAS) population (171)

- Met all the study entry criteria
- Subjects were considered for inclusion, independent of the success of deployment of the StarClose

Per Protocol (PP) population (156)

- Met all the study entry criteria
- StarClose was used successfully to close the arterial puncture site

Ultrasound Sub-Study (34)

Safety & Effectiveness Results

RISE SAFETY & EFFICACY ENDPOINTS	“FAS” Population N=171	“PP” Population N=156	CLIP Diagnostic Arm N=136
Median Time to Ambulation	6.25 min	5.9 min	134 min**
Mean Time to Ambulation	21.9 min	8.3 min	163 min**
Median Time to Hemostasis	3.23 min*	3.17 min*	0.28 min
Mean Time to Hemostasis	4.1 min*	3.5 min*	1.46 min
Mean Time to Dischargeability (Post-ambulation)	65.9 min	60.8 min	Not Measured
Mean Time to Dischargeability (Post-deployment)	89.7 min	73.0 min	212 min
Major Complications through 30 Days	0%	0%	0%
Minor Complications through 30 Days	2.3%	1.9%	2.2%
Procedure Success	100.0%	100.0%	100.0%
Device Success	91.2%***	100.0%	94.1%

* RISE subjects received a protocol-required 3 minutes groin hold; as a result Mean Time to Hemostasis was 3 minutes longer than for CLIP subjects.

** CLIP Diagnostic patients who were randomized to StarClose device were asked to ambulate 2 hours after the procedure was complete.

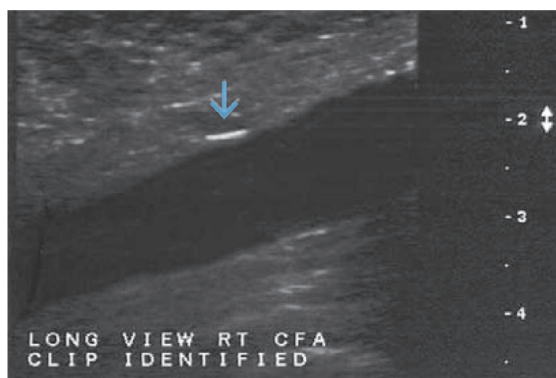
*** Majority of the device failure was due to access site oozing that needed greater than 5 minutes adjunctive compression. NO major complications were observed.

NOTE: Clinical data from CLIP and RISE are applicable to both StarClose and StarClose SE Vascular Closure System.

Ultrasound Sub-Study

- All (100%) subjects who enrolled and completed the 30-day follow-up (32/34) demonstrated patency of the access site artery and the common femoral artery.

Ultrasound Image Post StarClose



- Echo-dense StarClose Clip can be seen above the free flow of arterial blood as noted by the arrow.

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Please contact your local representative for more information.

Abbott Vascular International BVBA

Park Lane
Culliganlaan 2B, 1831 Diegem
BELGIUM

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