

SafeOp™

NEURAL INFORMATIX SYSTEM



OBJECTIVE • REAL-TIME • ACTIONABLE

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Introducing ATEC's SafeOp Neural Informatix System, providing surgeons real-time, actionable information to detect and monitor the health of nerves at risk during surgery.



Integrated Procedural Solutions

The SafeOp system and proprietary peripheral devices are designed to seamlessly integrate critical neural information into ATEC procedural solutions.

Lateral Approach Surgery

Nerve Identification

Real-time tEMG nerve detection provides reliable information regarding the direction and proximity of relevant neural anatomy.



Nerve Health

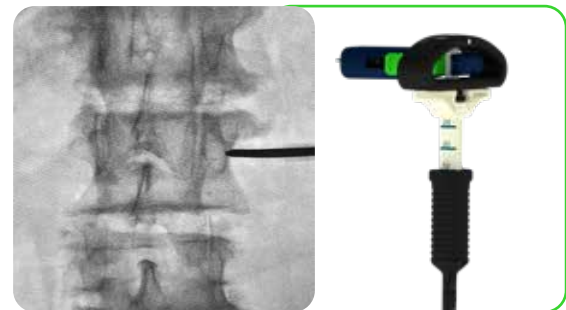
Powered by advanced signal processing, SafeOp delivers an unparalleled ability to monitor femoral nerve health throughout lateral procedures.



Invictus™ Posterior Fixation

Dynamic tEMG technology provides real-time feedback during pedicle preparation and screw placement to reduce the risk of pedicle breach.

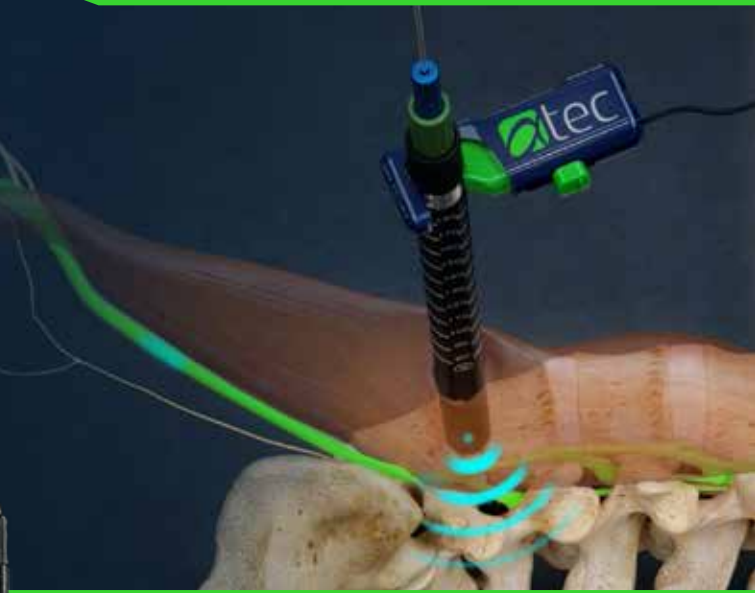
Invictus MIS Fixation



Invictus SingleStep™ Fixation



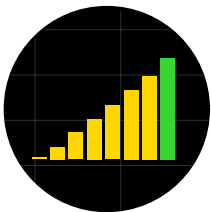
SafeOp tEMG: Fast, Reliable Nerve Identification



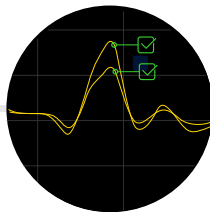
VRT Algorithm:

SafeOp's proprietary Validated Response Thresholding (VRT) algorithm is designed to deliver industry-leading nerve detection while reducing the incidence of false positive responses.

Fast, reliable, discrete neural information



Fast
Stimulation ramps from below threshold at a frequency 4x faster than competitive systems.



Reliable
Acquired threshold responses are validated with subsequent stimuli for reproducible results.



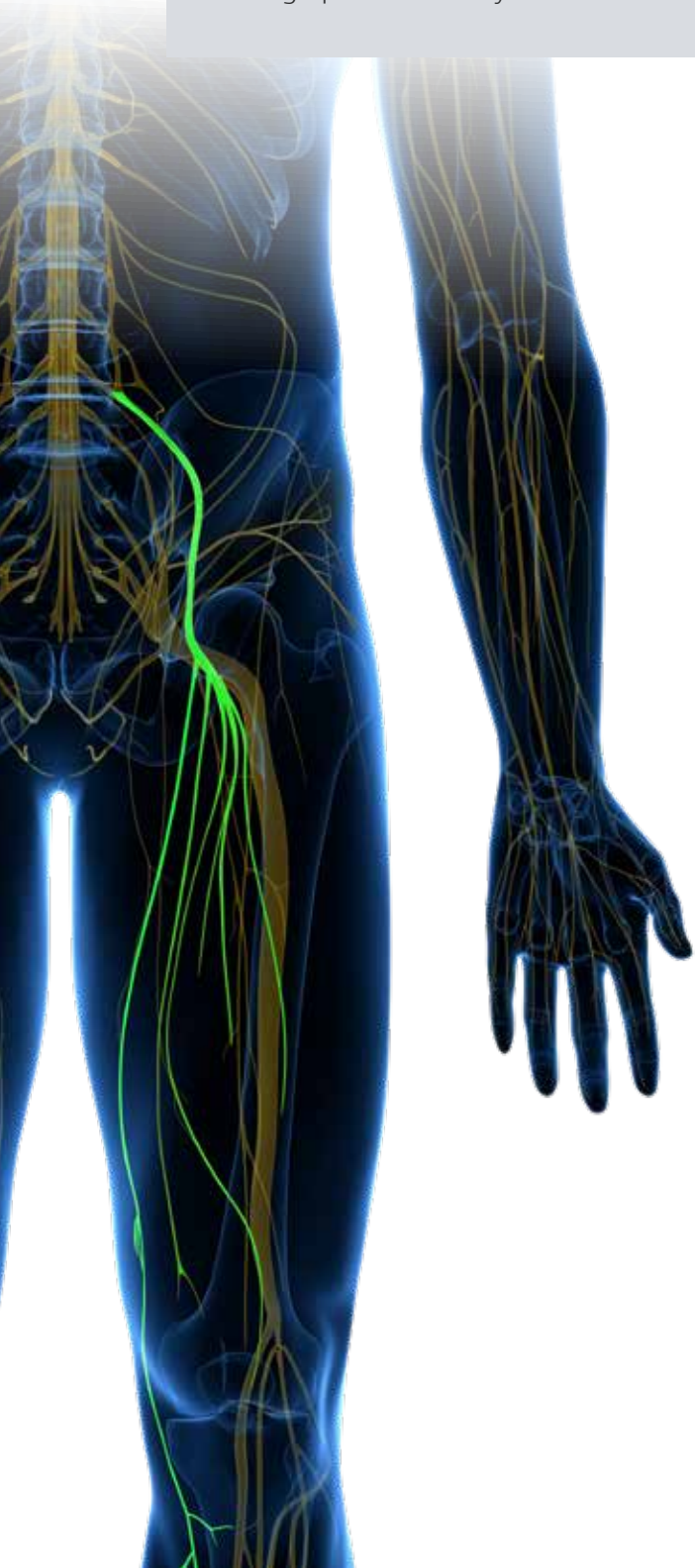
Discrete
Discrete threshold values are communicated audibly and visually.

Triggered EMG is critical to lateral surgery, but alone is not sufficient.

Femoral nerve complications persist.

Thigh paresthesia/dysesthesia: **16% to 36%**¹

Quadriceps palsy: **1.6% to 5.1%**¹



Femoral Nerve Health Monitoring with Saphenous Nerve SSEP

- Alternative methods to monitor the femoral nerve with free-run EMG, repeated tEMG, and MEP have been shown to be insufficient.²⁻⁴
- SSEP has been observed to have >95% sensitivity and specificity when used appropriately to monitor relevant neural structures.⁵
- Saphenous SSEP has been shown to have high positive and negative predictive value for femoral nerve complications in lateral surgery but responses are difficult to acquire with conventional systems.⁶

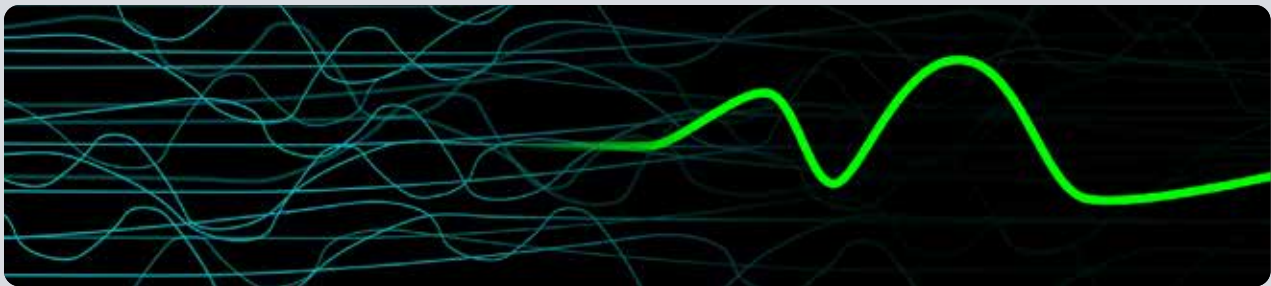
Technical Challenges with Saphenous Nerve SSEP

- Small saphenous responses are challenging to monitor.
- Delays from averaging reduce the opportunity for intervention.
- Variability in setup and interpretation lead to subjective information.

SafeOp SSEP: designed to provide actionable femoral nerve health monitoring

Advanced Signal Processing

Every element of SafeOp is optimized to provide reproducible saphenous SSEP to monitor femoral nerve health. A combination of cutting edge signal amplifiers and filters, proprietary waveform classifiers, and predefined SSEP parameters enable SafeOp to reproducibly monitor the small signals generated by the saphenous nerve.

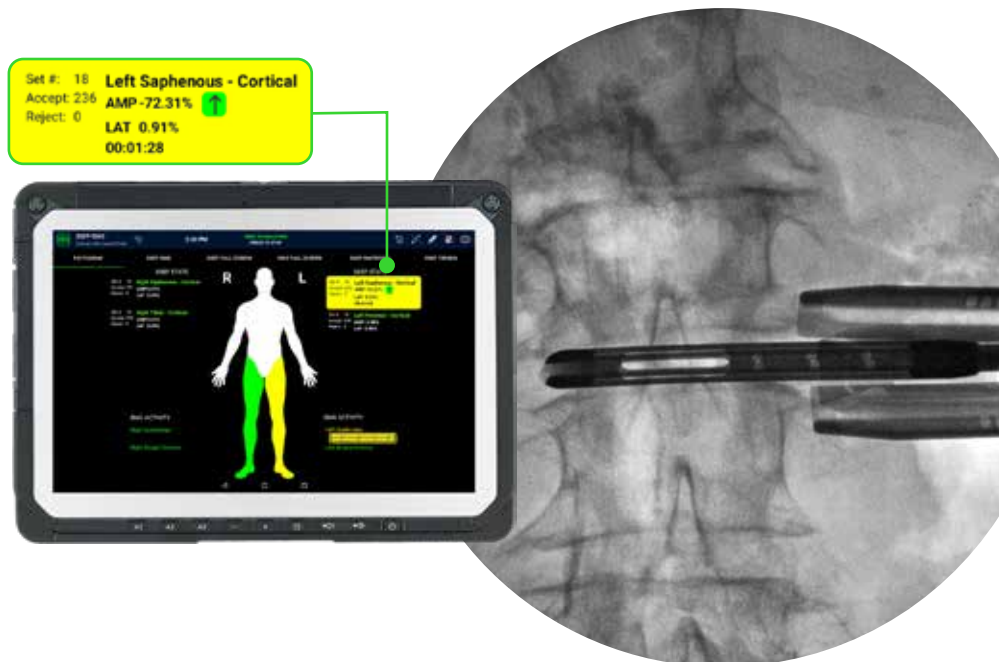


Objective SSEP Developed for Lateral Surgery

The risks associated with femoral nerve complications in lateral spine surgery have been well documented.¹ SafeOp's saphenous SSEP leverages novel waveform averaging to provide objective, real-time information on the integrity of the femoral nerve.

Actionable SSEP Information

- Audible and visual response change alerts
- Real-time display of SSEP amplitude and latency
- Response trend indicators



Delivered on an Integrated, Modern Platform



1

Integrated SSEP and EMG information

2

Integrated into ATEC procedural platforms

3

Integrated into the OR with small form factor and wireless connectivity



Actionable Intraoperative Information

With ATEC's SafeOp Neural Informatix System, spine surgeons have access to actionable information to help detect and monitor the health of nerves at risk during a procedure.

- Fast, reliable tEMG nerve identification
- Objective, actionable femoral nerve monitoring
- Seamless integration into the procedure



SafeOp FAQ

What were the specific findings of the saphenous SSEP study by Silverstein et al?

- In 41 cases with monitorable saphenous responses, 5 resulted in changes from baseline.
- In 1/5 cases, the retractor was adjusted and potentials returned to baseline with no postoperative deficits.
- In 3 of the 4 cases with persistent saphenous changes, patients woke with post-op deficits.
- Various SSEP settings configurations were used and 5 of 46 total cases were not able to obtain baselines.

How can I get more information on SafeOp and see a live demonstration?

- SafeOp is an integral part of ATEC's Visiting Surgeon Program and other surgeon education avenues including in-person discussion, product demonstration, and lab-based training.

How is SafeOp procured/deployed to support surgery?

- The SafeOp System will be provided on a loaner or consignment basis to support ATEC surgeries, and brought to the facility by an ATEC sales representative.

How are relevant resources trained to use the SafeOp System?

- SafeOp's field training program for sales representatives and facility personnel comprises online modules and in person training lead by a dedicated, CNIM Certified field training team.

References

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