

# SafeOp™

NEURAL INFORMATIX SYSTEM



OBJECTIVE • REAL-TIME • ACTIONABLE

# SafeOp™

NEURAL INFORMATIX SYSTEM

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

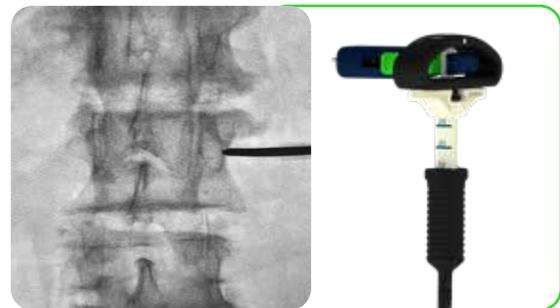
Powered by advanced signal processing, SafeOp delivers an unparalleled ability to monitor femoral nerve health throughout lateral procedures.



### Invictus™ Posterior Fixation

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

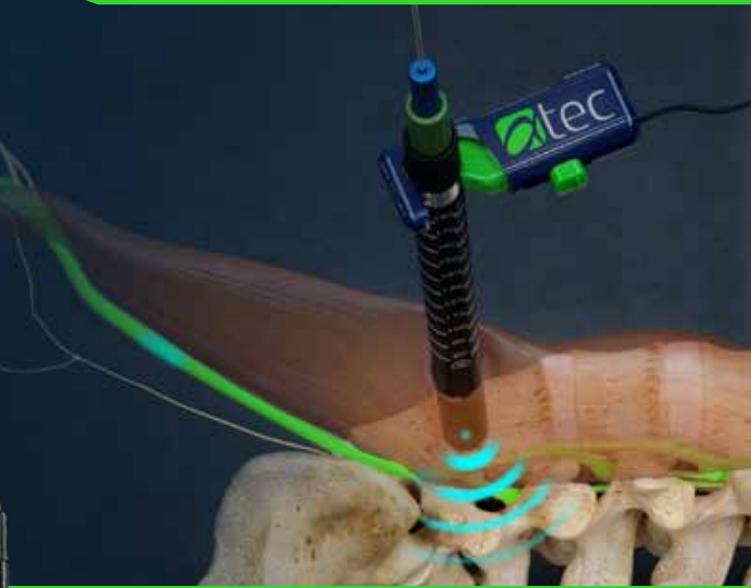
#### Invictus MIS Fixation



#### Invictus SingleStep™ Fixation



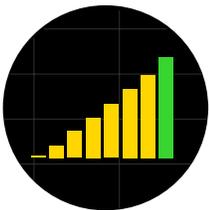
# SafeOp tEMG: Fast, Reliable Nerve Identification



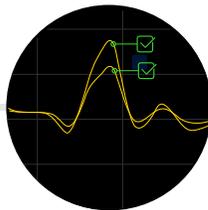
## VRT Algorithm:

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.



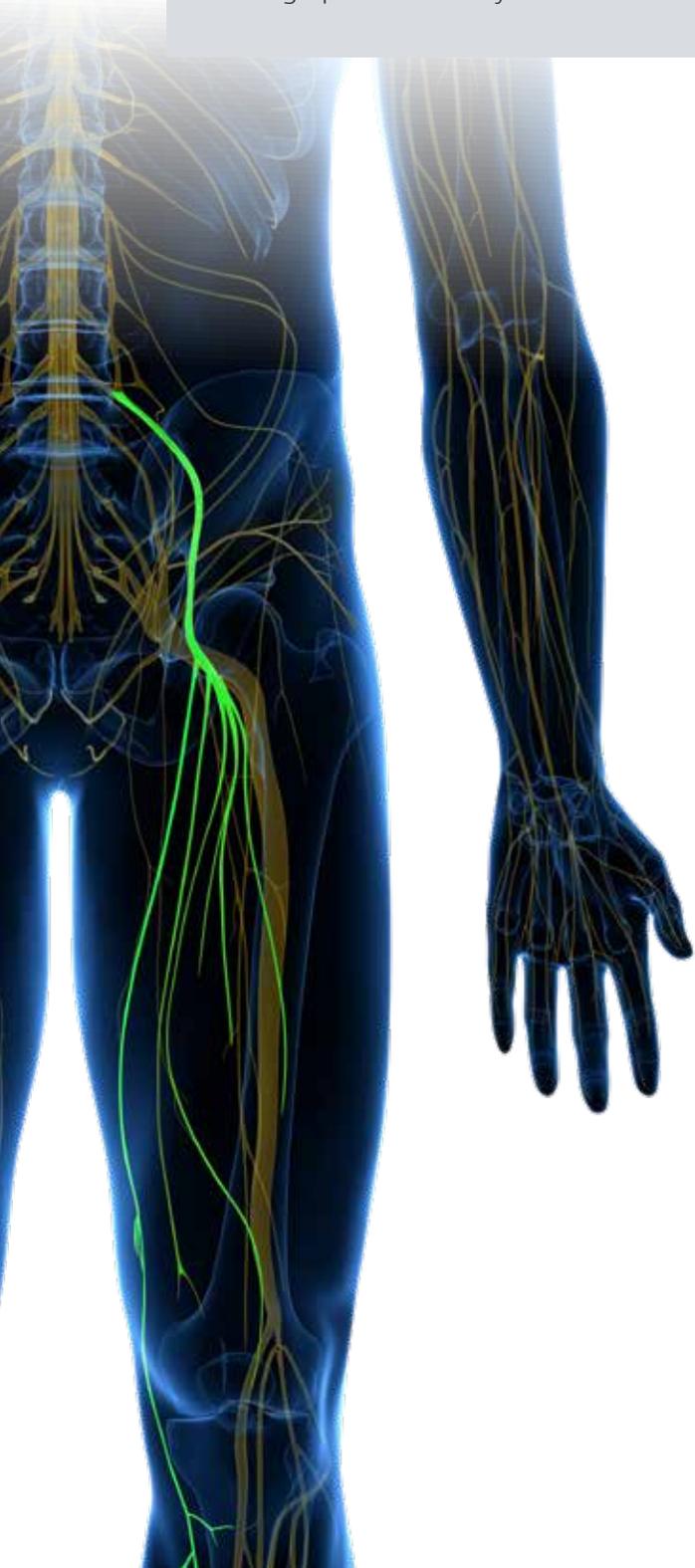
**Discrete**  
Discrete threshold values are communicated audibly and visually.

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

## Femoral nerve complications persist.

Thigh paresthesia/dysesthesia: **16% to 36%**<sup>1</sup>

Quadriceps palsy: **1.6% to 5.1%**<sup>1</sup>



---

## 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.<sup>2-4</sup>
- SSEP has been observed to have >95% sensitivity and specificity when used appropriately to monitor relevant neural structures.<sup>5</sup>
- 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.<sup>6</sup>

---

## 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.

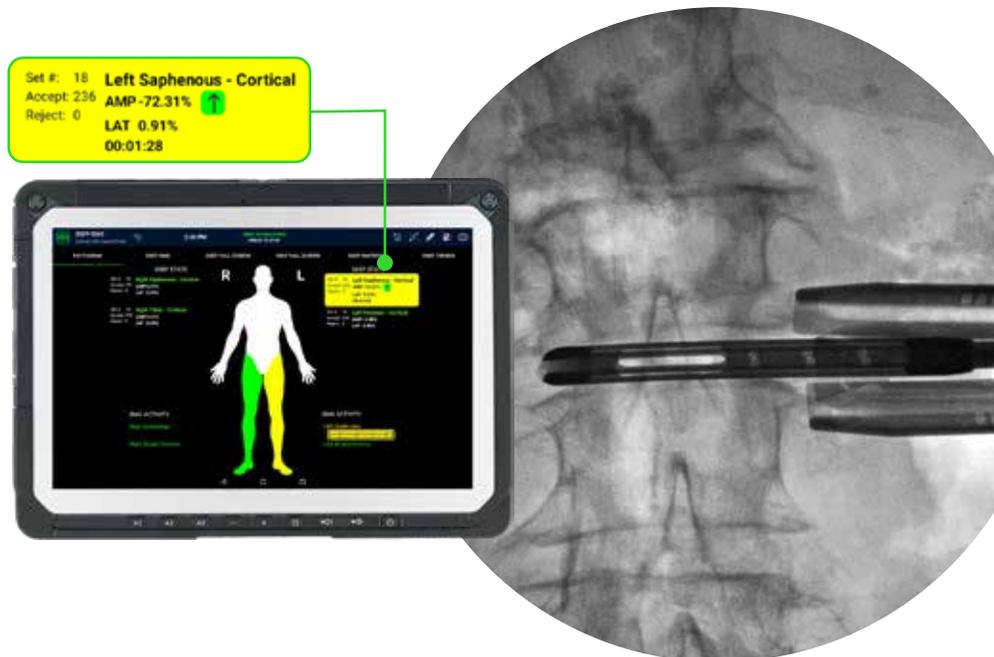


## Objective SSEP Developed for Lateral Surgery

The risks associated with femoral nerve complications in lateral spine surgery have been well documented.<sup>1</sup> 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

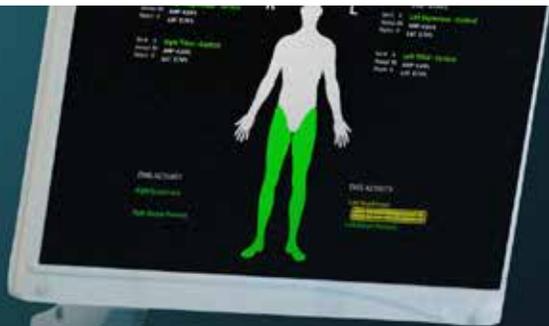
**Integrated** SSEP and EMG information

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

1. Lehmen JA, Gerber EJ. MIS lateral spine surgery: a systematic literature review of complications, outcomes, and economics. *Eur Spine J* 2015;24(Suppl 3):S287-313.
2. Gunnarsson T, Krassioukov AV, Sarjeant R, et al. Real-time continuous intraoperative electromyographic and somatosensory evoked potential recordings in spinal surgery: correlation of clinical and electrophysiologic findings in a prospective, consecutive series of 213 cases. *Spine* 2004;29:677-84.
3. Uribe JS, Isaacs RE, Youssef JA, et al. SOLAS Degenerative Study Group. Can triggered electromyography monitoring throughout retraction predict postoperative symptomatic neuropraxia after XLIF? Results from a prospective multicenter trial. *Eur Spine J* 2015;24(Suppl 3):S378-85.
4. Houten JK, Alexandre LC, Nasser R, et al. Nerve injury during the transpoas approach for lumbar fusion. *J Neurosurg Spine* 2011;15:280-4.
5. Thirumala PD, Bodily L, Tint D, et al. Somatosensory-evoked potential monitoring during instrument scoliosis corrective procedures: validity revised. *Spine J* 2014;14:1572-80.
6. Silverstein J, Mermelstein L, DeWal H, et al. Saphenous nerve somatosensory evoked potentials: A novel technique to monitor the femoral nerve during transpoas lumbar interbody fusion. *Spine* 2014;39(15):1254-60.



# SafeOp™

NEURAL INFORMATIX SYSTEM



**ALPHATEC SPINE  
CORPORATE HEADQUARTERS**  
5818 El Camino Real  
Carlsbad, California 92008

**CUSTOMER SERVICE**  
Toll Free: 800.922.1356  
Local: 760.431.9286  
Fax: 800.431.1624

The ATEC logo, Spine Approach Technologies, SafeOp, Alpha InformatiX, Invictus, and SingleStep are trademarks or registered trademarks of Alphatec Holdings, Inc., its affiliates and/or subsidiary companies. All other marks are the property of their owners. © 2019 Alphatec Spine, Inc. All rights reserved.