

Milestone Scientific's CompuFlo Instrument a safe alternative to current standards of care

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Publication in top ranked Anesthesia & Analgesia Journal compares CompuFlo pressure sensing to fluoroscopy and loss of resistance



Milestone Scientific Inc., a leading developer of computerized drug delivery instruments that provide painless and precise injections has announced the results of a four hundred patient clinical trial by researchers from the University of Miami, University of Texas and Northwestern University, and two prominent California-based pain clinics. Published-Ahead-of-Print in *Anesthesia & Analgesia* (the official Journal of the International Anesthesia Research Society), the randomized, controlled study compared the effectiveness of the CompuFlo® Epidural System ("CompuFlo") in labor and delivery and chronic pain management, where loss of resistance and fluoroscopy are the current standards of care. CompuFlo was found to be ninety-nine percent successful in objectively identifying the epidural space — even in challenging patients with a higher body mass index.

Performance of epidural anesthesia depends on successful identification of the epidural space. While fluoroscopy is associated with high success, it exposes patients to radiation and requires appropriate radiological equipment. Loss of resistance is subjective and consequently associated with higher failure rates and accidental dural punctures that require further treatment and interventions such as epidural blood patches.

CompuFlo features an innovative Dynamic Pressure Sensing technology® that differentiates tissue types by pressure signatures at the tip of the needle that are imperceptible by touch. This allows the instrument to accurately identify location and discriminate between true and false loss of resistance objectively and in real-time.

The data from this pivotal study confirms that CompuFlo is a safe and highly effective alternative to current standards of care. The instrument avoids patient radiation exposure when compared to fluoroscopy and demonstrated greater accuracy when compared to loss of resistance.

The clinical trial also found:

- CompuFlo's procedure time was the same as the current standard of care
- Labor and delivery epidurals performed with CompuFlo resulted in no accidental dural punctures, compared to four dural punctures with loss of resistance

Leonard Osser, Interim Chief Executive Officer of Milestone Scientific, commented, "We are committed to providing anesthesiologists and pain physicians technology that has the potential to improve success rates, reduce complications and lower costs. The findings of this clinical trial by five independent providers validates the CompuFlo epidural instrument as a safe, proven alternative to loss of resistance and fluoroscopy."

Study investigators include Ralf E. Gebhard, MD, Tobias Moeller-Bertram, MD, Douglas Dobecki, MD, Feyce Peralta, MD,

Evan G. Pivalizza, MBChB, FFASA, Madhumani Rupasinghe, MBBS, FRCA, Sanja Ilic, MD, and Mark Hochman, DDS (Milestone Scientific's Director of Clinical Affairs and Director of Research and Development).