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Milestone Medical Reports Ninth Published Study Reinforcing Efficacy of CompuFlo® Epidural Instrument as an Objective Tool to Identify the Epidural Space and Reduce Risk of Accidental Dural Puncture

LIVINGSTON, NJ, January 10, 2020 – Milestone Medical Inc. (WAR: MMD) today announced a new simulation study published in *Anesthesiology Research & Practice*, in an article entitled: [“Epidural Needle Extension through the Ligamentum Flavum Using the Standard versus the CompuFlo®-Assisted Loss of Resistance to Saline Technique: A Simulation Study.”](#)

The study verifies that the CompuFlo® Epidural System (“CompuFlo”) helps anesthesiologists to identify the epidural space with improved accuracy and less variation thus limiting over-advancement of an epidural needle that can lead to complications when inserting an epidural needle. Easier identification of the epidural space is essential to reducing the number of epidural attempts and risk of accidental dural puncture.

As reported in the article, accidental dural puncture is particularly troublesome in the obstetric population as more than half of all patients who experience accidental dural puncture with epidural needles may eventually develop a post-dural puncture headache¹. The article further reports that the overall quality of evidence for preventive measures is generally weak², and therefore good knowledge of lumbar anatomy together with a carefully performed technique are extremely important.

The simulation study evaluated the final position of a Tuohy epidural needle after penetration of analogue ligamentum flavum during the identification of the epidural space. Fifty-two expert anesthesiologists compared the use of CompuFlo® Epidural Instrument versus their standard loss-of-resistance technique. The results of the study demonstrated that an epidural technique performed with CompuFlo® resulted in very low variability between anesthesiologists, in which the needle was positioned in a safer location after entry into the epidural space. In comparison, using the standard loss-of-resistance technique the epidural needle was found to have greater variability in its final position as well as shown to be over-advanced into the epidural space when compared to the CompuFlo Epidural Instrument.

Mark Hochman, D.D.S., Inventor and Clinical Director for Milestone Medical, commented, “This is now the ninth published study further validating the CompuFlo Epidural System’s ability to safely and effectively identify the epidural space. This unique computer-controlled real-time pressure sensing technology provides anesthesiologists an objective and quantifiable technique to build confidence and success.”

The CompuFlo® Epidural Instrument gives anesthesia providers objective pressure and fluid measurements to verify the epidural space has been reached. This real-time Dynamic Pressure Sensing technology® reliably differentiates true from false loss of resistances. As noted in the article, the authors are not aware of any other devices on the market that can effectively distinguish between a true loss-of-resistance and a false loss-of-resistance as demonstrated by the CompuFlo Epidural Instrument. CompuFlo can connect to glass or plastic

1. B. E. Harrington, “Postdural puncture headache,” in NYSORA Textbook of Regional Anesthesia and Acute Pain Management, A. Hadzic, Ed., McGraw-Hill, New York, NY, USA, 2007.
2. R. Russel, C. Laxton, D. N. Lucas, J. Niewiarowski, M. Scrutton, and G. Stocks, “Treatment of obstetric postdural puncture headache. Part 1: conservative and pharmacological treatment,” *International Journal of Obstetric Anesthesia*, vol. 38, pp. 93–103, 2019.

LOR syringes so the anesthesia provider will receive additional objective information in real-time without sacrificing their LOR technique.

Study investigators include, Alessandra Coccoluto, Matteo Velardo, and Emanuele Capogna from the European School of Obstetric Anesthesia, Maternal Neonatal Simulation Centre, in Rome, Italy. The publication is available at: <https://www.hindawi.com/journals/arp/2020/9651627/>. Dr. Capogna is a member of Milestone Scientific's Advisory Board.

About Milestone Medical Inc.

Milestone Medical, Inc. has developed epidural and intra-articular drug delivery systems based on a patented, painless, computer-controlled injection and drug delivery technology originally developed by Milestone Scientific, Inc. Development of both the epidural and intra-articular instruments is now complete. The Company was granted the FDA marketing clearance of the epidural instrument in U.S. and is currently pursuing regulatory approval for intra-articular instrument in the U.S. Milestone Medical received CE Mark approval to sell and market its intra-articular and epidural instruments across European Union. For more information please visit www.medicalmilestone.com.

Safe Harbor Statement

This press release contains forward-looking statements regarding the timing and financial impact of Milestone's ability to implement its business plan, expected revenues, timing of regulatory approvals and future success. These statements involve a number of risks and uncertainties and are based on assumptions involving judgments with respect to future economic, competitive and market conditions, future business decisions and regulatory developments, all of which are difficult or impossible to predict accurately and many of which are beyond Milestone's control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are general economic conditions, failure to achieve expected revenue growth, changes in our operating expenses, adverse patent rulings, FDA or legal developments, competitive pressures, changes in customer and market requirements and standards, and the risk factors detailed from time to time in Milestone's periodic filings with the Securities and Exchange Commission, including without limitation, Milestone's Annual Report for the year ended December 31, 2018. The forward-looking statements in this press release are based upon management's reasonable belief as of the date hereof. Milestone undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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