

MDoloris Medical Systems announces the regulatory clearance and the upcoming launch of its Analgesia Nociception Index platform in Japan with Heiwa Bussan.

Paris, November 17, 2021 - MDoloris Medical Systems, a leader in the field of objective pain monitoring during anesthesia, announces today the regulatory clearance and marketing approval of its HFVI MOC-9, High Frequency Variability Index monitor, in Japan. MDoloris' HFVI MOC-9 Technology is the first monitoring solution for patients going through analgosedation and anesthesia in Japan.

The HFVI MOC-9 is a solution developed by MDoloris for Masimo (NASDAQ: MASI) for integration into its Root patient monitoring and connectivity hub, making it a full brain monitoring system. HFVI is a parameter obtained from the Heart Rate Variability, which is the same as ANI, Analgesia Nociception Index, being popular in Europe, that helps clinicians to assess the parasympathetic activity of patients undergoing surgery or intensive care in Japan.

“We are excited by this additional major milestone successfully passed by MDoloris in 2021 in Asia Pacific after the obtention of reimbursement and successful sales launch in South Korea, despite the pandemic impact. Thanks to the fantastic job performed with Heiwa Bussan, the exclusive business partner for both Masimo and MDoloris in Japan, we can look forward to a strong product launch and subsequent growth in one of the largest markets for our solutions.” declares Fabien Pagniez CEO and founder of MDoloris Medical System.

About the Analgesia Nociception Index

ANI is a parameter obtained from the Heart Rate Variability that helps clinicians to assess the Autonomic Nervous System, guiding the clinicians to titrate their analgesics during the surgery and anesthesia. This improves postoperative pain, PONV scores, shivering scores, and reducing post-operative opioids use (1), as well as, hospital stays (2) and may reduce the Montreal scales values (3), a scale used to assess post-operative cognitive disorders.



About MDoloris Medical Systems

MDoloris Medical Systems, a venture-backed French company, is the first worldwide company to be able to provide clinicians continuous and non-invasive surgical stress monitoring medical devices of the patient's parasympathetic tone. MDoloris is present in more than 70 countries and has benefited to more than 300 000 patients.

About Heiwa Bussan

Heiwa Bussan, the Japan-based import and sales company of medical devices, has been dealing with state-of-art medical devices mainly for cardiovascular and other surgeries related area since 1964 and expands its business to anesthesia and intensive care fields in Japan.

“We are thrilled to become the exclusive business partner of Mdoloris in Japan. The Japanese clinicians are extremely interested in the innovative and unique technology of Mdoloris which addresses the last unmet need of general anesthesia. We expect this technology will bring obvious clinical benefits and cost-effective outcomes. Heiwa Bussan has just become the only Japanese company being able to answer this need in the real world. Thereafter, we are extremely excited by the sales potential of such an innovative product”, declares Shinichi Hasuda, Representative Director of Heiwa Bussan.

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