



K2M Launches the MESA(R) 2 Deformity Spinal System in the US

The Next-Generation MESA System is Poised to Address the Most Difficult Correction Maneuvers for Complex Spinal Pathologies

LEESBURG, Va., July 2, 2015 (GLOBE NEWSWIRE) -- K2M Group Holdings, Inc. (Nasdaq:KTWO) (the "Company" or "K2M"), a global medical device company focused on designing, developing and commercializing innovative and proprietary complex spine technologies, techniques and minimally invasive procedures, today announced the U.S. commercial launch of the MESA[®] 2 Deformity Spinal System, the Company's next-generation pedicle screw system designed to address the most complex spinal pathologies. MESA 2 carries forward the hallmarks of the Company's complex spine MESA technology, while offering new capabilities to enhance user experience.

"Following a successful Alpha phase, we are excited to announce the commercial launch of our MESA 2 Deformity Spinal System and the upcoming rollout across the United States," stated Eric Major, K2M's President and CEO. "MESA 2 is the much-anticipated upgrade to our flagship MESA platform and is designed to save time by cutting the number of basic surgical steps in half. We take great pride in being viewed by the surgeon community as a company that is focused on innovation and differentiation, and we remain committed to developing products that will help improve the lives of patients suffering from the most complicated spinal pathologies."

"MESA 2 includes enhancements to the original MESA technology and instrumentation," said Laurel C. Blakemore, MD, chief and associate professor of pediatric orthopaedics in the department of orthopaedics at the University of Florida. "This new system is yet another example of K2M's pioneering efforts to design innovative solutions for correcting spinal deformities."

The MESA 2 Deformity Spinal System features the next-generation MESA 2 screw, a top-loading, low-profile screw that offers a dual-lead thread pattern for fast insertion. K2M's MESA Technology also features Zero-Torque Technology[®], which offers surgeons the ability to one-step lock without torsional stress being applied to the spine. Both deformity polyaxial and uniplanar screws are available in this new system.

Designed to increase efficiency, MESA 2 also features a variety of easy-to-use reduction and spinal manipulation instruments. The Quicket[™] is an updated, quicker version of K2M's breakthrough Cricket[®] rod reduction technology that provides quick on/off capabilities, while correcting the spine in all three planes. Additionally, the Over Quicket Final Locker allows for one-step locking over the Quicket, thus eliminating the need to partial lock.

In January, the Company announced it had obtained 510(k) clearance from the U.S. Food and Drug Administration to market MESA 2. To date, nearly 70 surgical cases using MESA 2 have been completed.

For more information, visit www.K2M.com.

About K2M

K2M Group Holdings, Inc. is a global medical device company focused on designing, developing and commercializing innovative complex spine and minimally invasive spine technologies and techniques used by spine surgeons to treat some of the most difficult and challenging spinal pathologies. K2M has leveraged these core competencies to bring to market an increasing number of products for patients suffering from degenerative spinal conditions. These technologies and techniques, in combination with a robust product pipeline, enable the Company to favorably compete in the global spinal surgery market. Additional information is available online at www.K2M.com.

Forward-Looking Statements

This press release contains forward-looking statements that reflect our current views with respect to, among other things, our operations and financial performance. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "could," "seeks," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward looking statements are subject to various risks and uncertainties including, among other things: our ability to achieve or sustain profitability; our ability to successfully demonstrate the merits of our technologies; pricing pressure from our competitors, hospitals and changes in third-party coverage and reimbursement; competition and our ability to develop and commercialize new products; aggregation of hospital purchasing from collaboration and consolidation; hospitals and other healthcare providers may be unable to obtain adequate coverage and reimbursement for procedures performed using our products; the safety and efficacy of our products is not yet supported by long-term clinical data; our dependence on a limited number of third-party suppliers; our ability to maintain and expand our network of direct sales employees, independent sales agencies and international distributors; the proliferation of physician-owned distributorships; concentration of sales from a limited number of spinal systems or products that incorporate these technologies; loss of the services of key members of our senior management, consultants or personnel; ability to enhance our product offerings through our research and development efforts; failure to properly manage our anticipated growth; acquisitions of or investments in new or complementary businesses, products or technologies; ability to train surgeons on the safe and appropriate use of our products; requirements to maintain high levels of inventory; impairment of our goodwill or intangible assets; disruptions in our information technology systems; any disruption in operations at our headquarters facility or an ability to ship a sufficient number of our products to meet demand; ability to strengthen our brand; fluctuations in insurance cost and availability; extensive governmental regulation; failure to obtain or maintain regulatory approvals and clearances; requirements for new 510(k) clearances, premarket approvals or new or amended CE Certificates of Conformity; medical device reporting regulations, voluntary corrective actions or agency enforcement actions; a recall of our products or the discovery of serious safety issues with our products; possible enforcement action if we engage in improper marketing or promotion of our products; the misuse or off-label use of our products; delays or failures in any future clinical trials; the results of clinical trials; procurement and use of allograft bone tissue; environmental laws and regulations; compliance by us or our sales representatives with fraud and abuse laws; U.S. legislative or regulatory healthcare reforms; medical device tax provisions in the healthcare reform laws; our need to generate significant sales to become profitable; potential fluctuations in sales volumes and our results of operations may fluctuate over the course of the year; uncertainty in our future capital needs; continuing worldwide economic instability; our inability to protect our intellectual property rights; our reliance on patent rights that we either license from others or have obtained through assignments; our patent litigation; the outcome of potential claims that we, our employees, our independent sales agencies or our distributors have wrongfully used or disclosed alleged trade secrets or are in breach of non-competition or non-solicitation agreements with our competitors; potential product liability lawsuits; operating risks relating to our international operations; our ability to comply with the Foreign Corrupt Practices Act and similar laws associated with our activities outside the United States; control by and possible conflicts of interest with our controlling shareholder; increased costs and additional regulations and requirements as a result of becoming a public company; our ability to implement and maintain effective internal control over financial reporting in the future; the potential impact of any future acquisitions, mergers, dispositions, joint ventures, investments or other strategic transactions we may make; and other risks and uncertainties, including those described under the section entitled "Risk Factors" in our registration statement, filed with the SEC on January 29, 2015 as such factors may be updated from time to time in our periodic filings with the SEC, which are accessible on the SEC's website at www.sec.gov. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this release and our filings with the SEC.

We operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this release. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this press release relate only to events as of the date on which the statements are made. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward looking statements and you should not place undue reliance on our forward-looking statements.

Find K2M on Facebook: <https://www.facebook.com/K2MInc>

Follow K2M on Twitter: <http://twitter.com/K2MInc>

Watch K2M on YouTube: <http://www.youtube.com/user/K2MInc>

CONTACT: Media Contact

Zeno Group on behalf of K2M Group Holdings, Inc.

Marcie Kohenak, 202-965-7811

Marcie.Kohenak@ZenoGroup.com



Source: K2M Group Holdings, Inc.

News Provided by Acquire Media